IMPROVEMENT OF GENERAL DESIGN THEORY AND METHODOLOGY WITH ITS APPLICATION TO DESIGN OF A RETRACTOR FOR VENTRAL HERNIA REPAIR SURGERY

A Thesis Submitted to the College of Graduate and Postdoctoral Studies

In Partial Fulfillment of the Requirements for the Degree of Master of Science

In the Division of Biomedical Engineering

University of Saskatchewan

Saskatoon

By

Zhenwei Dai

PERMISSION TO USE

In presenting this thesis in partial fulfillment of the requirements for a graduate degree from the University of Saskatchewan, I agree that the libraries of this university may make it freely available for inspection. I further agree that permission for copying of this thesis in any manner, in whole or in part, for scholarly purposes may be granted by the professor or professors who supervised my thesis work, or in their absence, by the head of the department or the dean of the college in which my thesis work was done. It is understood that any copying or publication or use of this thesis or parts thereof for financial gain shall not be allowed without my written permission. It is also understood that due recognition shall be given to me and to the University of Saskatchewan in any scholarly use which may be made of any material in my thesis. Request for permission to copy or to make other use of material in this thesis in whole or in part should be addressed to:

Chair of Division of Biomedical Engineering
College of Engineering, 57 Campus Drive
University of Saskatchewan
Saskatoon, Saskatchewan S7N 5A9 Canada

OR

Dean
College of Graduate and Postdoctoral Studies
University of Saskatchewan
116 Thorvaldson Building, 110 Science Place
Saskatoon, Saskatchewan S7N 5C9 Canada

ABSTRACT

Open surgery is an efficient way to cure massive ventral hernias in the clinic. During the surgical process, a spatula is used to prevent intestine tissues from damage of suture passer, possibly causing damage and taking time to address the spatula. Therefore, a new prototype, which could address both issues, is under consideration. In order to design the new prototype that satisfies clinical use, this study was based on the retractor design by Dr. Luo (Luo's retractor for short), which nevertheless had many shortcomings. An observation was made to these shortcomings that they are partially due to the ad-hoc design process taken to result in Luo's retractor). This drove the research of this thesis into a close examination of the general design theory and methodology (DTM) in literature, aiming at improvements of DTM so that it is possible to apply the DTM to improve Luo's retractor.

In this thesis, the general design theory and methodology, such as Axiomatic Design Theory (ADT) and Systematic Design Procedure (SDP), was examined closely. Several problems with them, e.g., missing a guideline to identify the so-called general function in SDP, missing a guideline to handle constraints in ADT, lack of a more formal model to capture design requirements, etc., were identified and studied. Specifically, a novel model to represent a design more formally was proposed, and a new general design process model was developed. The design of the retractor was then carried out by following the proposed general design process model with the improved DTM, which resulted in an improved retractor. The prototype of the new retractor was tested clinically with the help of surgeon (Dr. Luo) as well as simulated with the help of the finite element software.

Several conclusions can be drawn from this study and they are: (1) the new retractor is a viable device and is promising for further commercialization; (2) the general design theory and methodology is now more rational, formal and robust, ready for applications and for further development towards automating the general design process.

This thesis has made the following contributions to the field of medical device and to the field of general design theory and methodology. In the first field, a new medical device, i.e., retractor, is created and it will improve the ventral hernia repair surgery in terms of efficiency (time reduction by 37.5%). In the second field, this thesis provided a revised design theory and methodology that combines ADT and SDP, which may be called ADT-SDP, and has provided guidelines of how the ADT-SDP can be used for practical design problems.

ACKNOWLEDGEMENTS

The journey of research is not an easy progress, which is a scientific training. I appreciate that so many people accompany with me along in this journey. I would like to show my great appreciation to my supervisors, Chris Zhang and Yigang Luo, whose enthusiasm, encouragement, patience and guidance have a great influence on my research work. Their knowledge impresses me so much and will continue to impact my life.

I would like to acknowledge my advisory committee members, Daniel Chen and Seok-Bum Ko, who keep the attitude of patience and support in the process.

I would like to thank my friends, Ang Chen, Charles Yuan, Hasan Majumdar, Ramesh Ramanujam and Saman Rahbar. They have given me significant helps for pursuing my Master of Science degree in the University of Saskatchewan. I cherish every moment spent with you guys and look forward to spending time with each of you in the future.

Finally, I would like to appreciate my lovely parents. Because of their financial support, it makes it possible for me to pursue my master's degree in Canada. Because of their support, I have never given up when meeting difficulties along this study journey. I am deeply thankful for their input for me.

DEDICATION

To:

My father, Puxiang Dai, and

My mother, Xiuhua

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1

INTRODUCTION

1.1 Background and Motivation

Ventral hernia is a bulge in the abdomen caused by abdominal cavity contents pushing abdominal wall layers. It randomly happens at any area on the abdominal wall. Majority of ventral hernias are incisional hernias meaning that they occurred at past incompletely-healed surgical incisions. But not all ventral hernias are incisional; some may occur due to trauma or congenital problems. Ventral hernias are abdominal tissues that penetrate weak spots of the abdominal wall (Ventral Hernia - Symptoms & Treatment, n.d.). Unfortunately, ventral hernias cannot heal by themselves, and they require surgery to push them back (Krause, 2018).

There are several treatment options available for the ventral hernia problem nowadays:

- Open surgery: A surgeon makes an incision in the abdominal wall, finds a hernia in the abdomen, separates it from the surrounding tissues, pushes the tissues back into place, and finally places a mesh patch on the weak area to keep intestines in place. Any parts of the intestines that have been destroyed by a hernia will be removed (Krause, 2018).
- Laparoscopic surgery: Several comparative small incisions are first made in the abdomen, then a thin and light scope is inserted through the incisions. A surgeon makes use of this instruments to fix the defect. In the repair, a mesh may or may not be employed to reinforce the weak spot (Krause, 2018).

In the above treatment options, it would be ideal if a ventral hernia could be repaired by laparoscopic technology, as this technology has the benefits (as opposed to the open surgical technology):

- less tissue trauma and smaller incisions,
- reduced postoperative pain,
- shorter hospital stays, and
- shorter recovery time.

Unfortunately, for large hernias, laparoscopic surgery is not effective. Large hernias are also called massive ventral hernias with their length or width being more than 15 centimeters (cm) or their overall area being 150 cm^2, according to Krause (2018).

Massive ventral hernias are not uncommon. Approximately 350,000-500,000 ventral hernia repairs including both open and laparoscopic surgeries are performed every year in the United States (Laparocopic Ventral Hernia Repair Patient Information From Sages, n.d.). Roughly half of them are open incisional repair treatments (Luo et al., 2017). For the open incisional surgery, the mean operative time is 80 min (min. 45, max.190) (Crovella, Bartone, & Fei, 2008).

In the ventral hernia repair procedure, a mesh is sewed underneath the abdominal wall to stop the tissues from pushing back. A suture passer, a sharpened needle, is used to sew the mesh to the inner wall of the abdomen, passing it through the abdominal wall to reach the mesh. On the mesh, there are a series of threads (Fig. 1.1). When the passer reaches the mesh, the surgeon takes the thread to the tip hole of the passer, and the passer is then withdrawn out of the abdominal wall to

form a stitch. As such, the mesh can be sewed on the inner wall of the abdominal. In this operation, there is a risk that the suture passer may accidentally hurt intestines underneath the abdominal wall. To avoid this risk, a thin sheet of metal called spatula is placed in the abdominal cavity between the inner wall of the abdomen and mesh (Fig. 1.2). The typical spatula is shown in Fig. 1.3 (Luo, et al., 2017). After the suture passer is penetrated through the wall of the abdomen, the spatula is supposed to prevent the passer from touching the intestine. For each stitch, the spatula needs to be placed to a right position, and the foregoing process is repeated for forming each stitch.

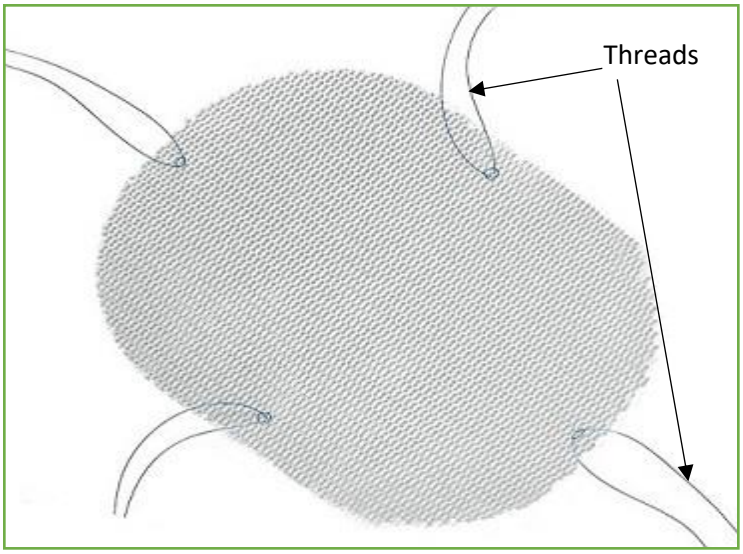


Figure 1.1 Mesh with thread

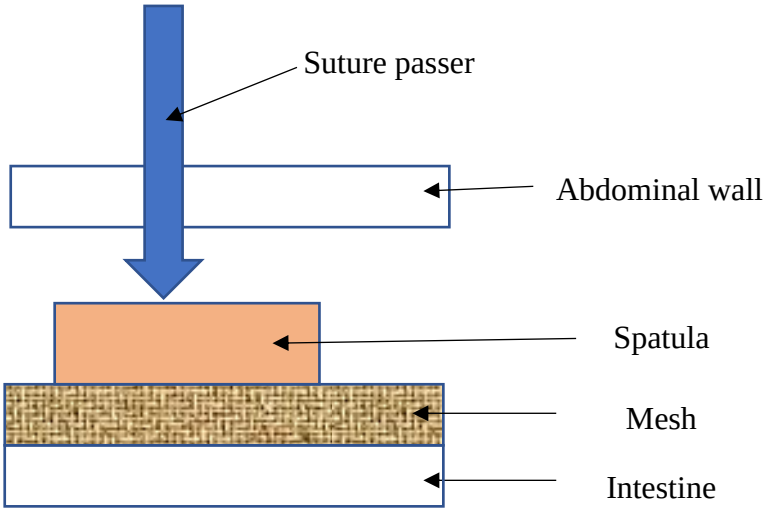


Figure 1.2 The open repair process for ventral hernia

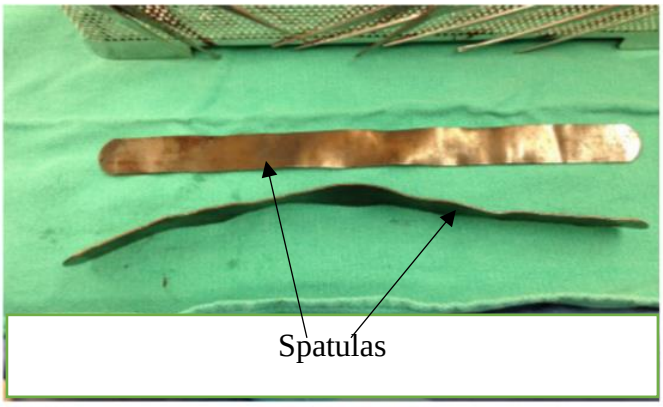


Figure 1.3 Currently available spatula device

There are several drawbacks with this spatula approach (Fig. 1.2), namely:

- it does not adequately protect the intestine from the suture passer,
- it relies on the physicians to coordinate both the operation of the suture passer and the placement of the spatula, and

- the surgery operation takes a longer time, as a series of reposition of the spatula is needed to cover the area of ventral hernia (Fig. 1.4).

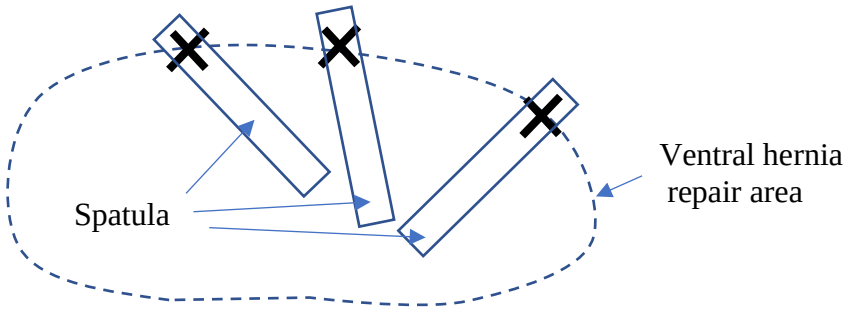


Figure 1.2 The schematic of the current operation with the spatula

Development of a new device to address the issues with the spatula was first attempted by Luo et al. (2017), and this new device is called retractor (Fig. 1.5). In Fig. 1.5, the retractor has several plates and it has two states: expanded state (Fig. 1.5b) and collapsed state (Fig. 1.5a). In the non-operation situation, the retractor is in the collapsed state, while in the operation situation, the retractor is in the expanded state. The collapsed state must be designed such that the entire retractor can be inserted through the incision opening of the abdominal wall, and ideally it is as small as possible. The size of the incision opening depends on the size of hernia. Fig. 1.6 shows an example of hernia along with the incision on the abdominal wall.

Luo's prototype has some areas identified for improvement. First, the material used in Luo's prototype was not biocompatible. Second, the whole device was still bulky and not easy to operate, especially the whole device is too thick to be readily placed in the cavity between the abdominal wall and the intestine.

This thesis was motivated to give a closer look into the ventral hernia surgery and to optimize the

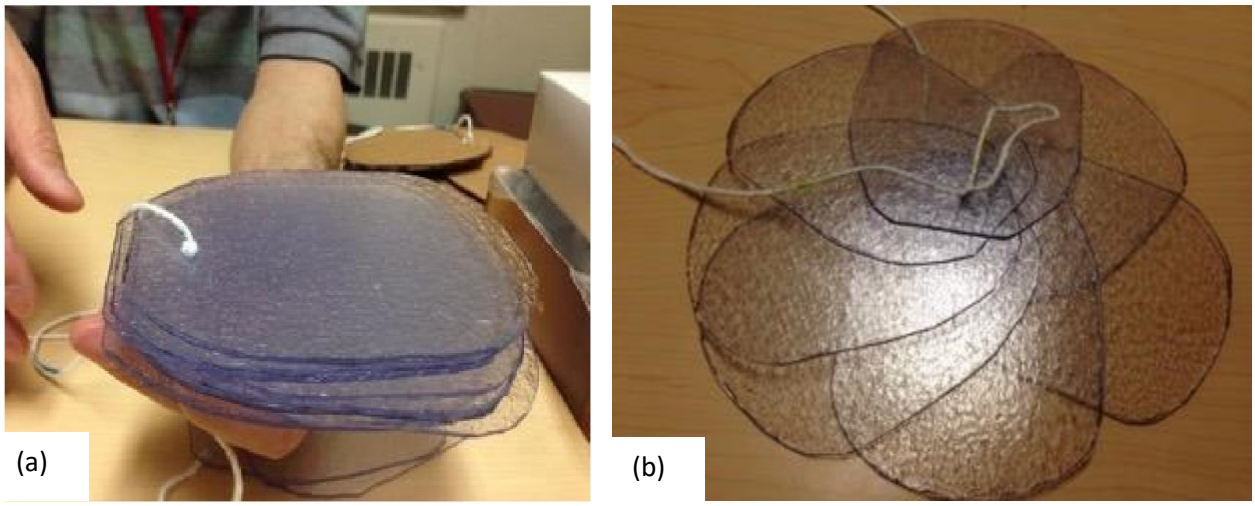


Figure 1.3 Luo's retractor. (a) the collapsed state; (b) the expanded state.

design of spatula, including Luo's retractor. To make the present work with some more generalized implication, hereafter the devices, such as spatula, retractor, and even mesh, are called **bio-devices** because they have the distinctive feature -- being in contact with biological systems such as human organs and tissues. This generalization may have dual-benefits. First, the existing knowledge for other instances of bio-device would be borrowed to design the retractor in this thesis study, and second, the knowledge generated from the design of the retractor could be utilized for other instances of bio-devices in future.

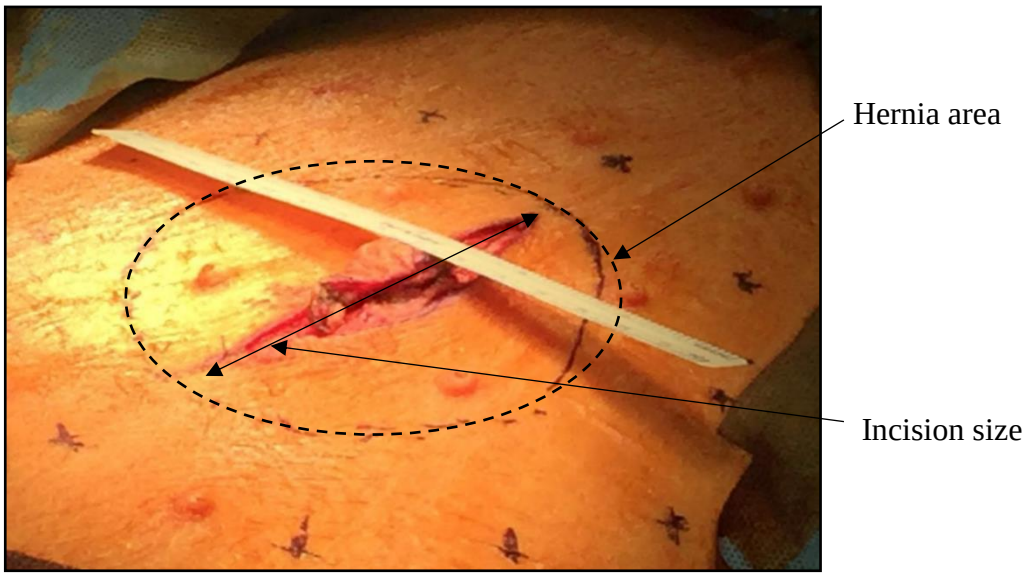


Figure 1.4 Hernia along with the incision

Driven by the motivation, the strategy taken in this thesis was to examine both general design theory and methodology and specific design methodology for bio-devices (i.e., the spatula or retractor in this case) in literature, for designing the retractor. A preliminary study revealed that there were many unresolved issues in general design theory and methodology for products. Therefore, this thesis was expected to address these issues as well, along with to develop the specific design theory and methodology for the bio-devices and the retractor.

1.2 Research Questions

The thesis study began with the following questions:

Question 1:

Is the general design theory and methodology in literature readily available for guiding the design process of bio-devices (e.g., retractor)?

The devices such as the retractor have the feature that they are necessary to be soft in the sense that first, Young's modulus of the material of the devices should be compatible with that of the human body, and second the interaction of the devices with human body should not damage human body. Such a kind of devices may be called soft devices (Chen, et al., 2017). In literature, there are many design theories and methodologies developed by researchers for general products. However, first there are still some confusions with those theories and methodologies in their applications (Zhang, Li, & Zettl, 2012), and second, there is no specialized design knowledge available for soft devices. Research into the answer to this question will have generalized implication to both general design theory and methodology and soft device design theory and methodology.

Question 2:

Is the current retractor design optimal in that it can achieve the best performance and meet all the function and constraint requirements?

It is observed that the current retractor device does not really follow any rational and systematic design process (Fan, Cai, Lin, & Zhang, 2015); in other words, the design seems to be ad-hoc, and thus there is room to optimize the design or there may potentially be some problems. For instance, while the plates of the retractor are expanded, they may damage the tissue. Additionally, the whole retractor seems bulky and it may require a large incision, thus increasing the degree of invasiveness.

1.3 Research Objective and Scope

The overall research objective was to develop a general methodology for designing soft devices and to apply this methodology to the retractor, in order to overcome the limitations of Luo's prototype. The following are the specific objectives of this thesis.

Objective 1: To clarify several unresolved issues in the general design theory and methodology, especially developing a more formal model (or notation) that can more precisely describe a design process, including technical specification.

ADT (Suh, 2010) stands for axiomatic design theory and SDP (Pahl, Beitz, & Feldhusen, 2007) stands for systematic design procedure. These two design approaches are combined into one approach called ADT-SDP (Muddada, 2014) based on the analysis of the relationship between the two approaches. This thesis conducted design by following ADT-SDP. The current literature had missed such a notation, which hindered a good practice of design. Furthermore, the guideline to conduct a design based on the ADT-SDP was incomplete, e.g., no guideline was existed about whether the evaluation of a design by Axiom I should be performed at the sub-functions at the same level of a functional decomposition lattice or at the leave level. Research into this objective was expected to produce the answer to Question 1.

Objective 2: To develop a complete requirement model or technical specification for the retractor, including the requirement on the softness of the retractor such that the retractor design can be evaluated quantitatively and objectively.

The research resulting from Objective 1 will be applied here. The requirement includes both the function and constraint parts. The research into this objective was expected to produce the answer to Question 2.

Objective 3: To design, fabricate and test or experiment the new retractor to explore its improved behavior along with its performance over Luo's retractor against the technical specification.

The existing retractor will be optimized. This covers optimal design, development, and testing. The new device will be evaluated based on the requirement model developed in the research into Objective 2.

The study was limited to the proof-of-concept rather than any commercial product.

1.4 Research Methodology

A thorough literature study of the general design theory and methodology in literature along with illustration with the help of practical design examples was taken to achieve Objective 1. This included the classification of issues and resolution of the issues. The ADT-SDP process was taken as a backbone, as it was proved to be effective in the precious work of Muddada (2014).

By generalization of Luo's prototype, the bio-device like retractor is a soft folding device, see the precious discussion particularly the two states of the retractor (collapsed state and expanded state).

Therefore, design theories and methodologies for soft devices and folding devices were also examined to achieve Objective 2 and Objective 3.

A series of experiments were conducted with the help of the surgeon (Dr. Y.G. Luo) in order to prove the effectiveness of design concepts for the retractor.

1.5 Outline of the thesis

The thesis consists of six chapters. The remaining five chapters are outlined as follows:

Chapter 2 offers a literature review to show further the necessity and significance of the objectives as mentioned before. The literature review focuses on general design theory and methodology, which includes axiomatic design technology (ADT), systematic design procedure (SDP), and incubating ADT-SDP approaches, design of soft device, which includes concept and examples of soft device, and design of folding device, which includes concept of folding principle and folding mechanism device, as well as medical protective devices, which includes applications for different purposes.

Chapter 3 presents several issues existing in the current ADT-SDP approach and introduces the representation of guidelines and notations to address the issues. As well, the illustration of guidelines and notations is demonstrated through a case study.

Chapter 4 presents a more comprehensive requirements specification for the retractor based on the outcome of Chapter 3.

Chapter 5 presents the conceptual design, embodiment design and detail design of a novel retractor. The simulation results are illustrated as well to assist the steps of design

Chapter 6 presents the fabrication process of the retractor device is displayed as well. In addition, several testing methods and results are illustrated in this chapter.

Chapter 7 concludes the thesis with discussions, consisting of the representation of notations and guidelines of the design process, the retractor contribution to the medical surgery, and future work.

CHAPTER 2

BACKGROUND AND LITERATURE REVIEW

In this chapter, the relevant background materials are discussed, including the general design theory and methodology, the design of soft devices, the design of folded devices, and medical protection devices.

2.1 General design theory and methodology

2.1.1 General design phase theory

The general design phase theory consists of four steps: the technical specification of requirements, concept design, embodiment design and detail design. For each step, it has different tasks. For the technical specification of requirements, it uses the technical terminology to represent the customer's voice of the requirement for his product; for concept design, it focuses on developing the working principle of the device under design to meet requirements in the technical specification; for embodiment design, it concentrates on developing the body structure of the device under design to embrace the working principle; for detail design, it develops a complete specification of the device under design ready for manufacturing or purchasing.

2.1.2 System decomposition: divide-and-conquer

Design can be viewed as problem-solving. To a complex problem (i.e. a complex requirement in the case of design), a division of this problem into a set of simple problems is needed. The so-called simple problem means that the problem has a solution. In the case of design, it refers to decomposition of a complex requirement into a set of simple requirements such that the simple requirements can be fulfilled by designs (or descriptions of devices). For the convenience of later discussions, the divide-and-conquer is called **DC Axiom**.

2.1.3 Axiomatic design theory

The axiomatic design theory consists of two parts: The Independent Axiom (Axiom I) and Information Axiom (Axiom II) (Suh, 2010).

- **Axiom I**: "Maintain the independence of the functional requirements (FRs)." (Axiomatic design, n.d.). In the following discussion, it is denoted as **ADT-Axiom I** for the convenience of discussions.
- **Axiom II**: "Minimize the information content of the design." (Axiomatic design, n.d.). In the following discussion, it is denoted as **ADT-Axiom II** for the convenience of discussions.

According to Fan et al. (2015), ADT-Axiom I is only applicable to the concept design phase. In this thesis, ADT-Axiom I is concentrated.

2.1.4 Systematic design procedure

The systematic design procedure (SDP) consists of two processes: function decomposition and device searching. According to Zhang (2018), the principle to conduct the function decomposition is the application of engineering common-sense. For instance, one should first design X, and then manufacture X based on the design of X (i.e., description of X). The principle to conduct the device searching is the match of the functional requirement and the function of the devices in the past design practice or based on the imagination of designers. To facilitate the device searching, SDP has a concept called general function and specific function (Pahl, Beitz, & Feldhusen, 2007). SDP also advocates the general design phase theory and has a step to check the physical compatibility among component devices or components that are designed to fulfill the functional requirements through the four design phases.

2.1.5 Integrated ADT-SDP (Muddada, 2014)

Muddada (2014) proposed to integrate ADT and SDP based on the observation that the two are complementary to each other in many ways. SDP provides a guideline to develop the function decomposition, and a guideline to probe the (conceptual) design solution. ADT, however, provides a means to perform the evaluation of design, including both the design requirement and design solution with ADT-Axiom I and ADT-Axiom II. Figure 2.1 shows the integrated ADT-SDP approach of Muddada (2014), where there are eight steps.

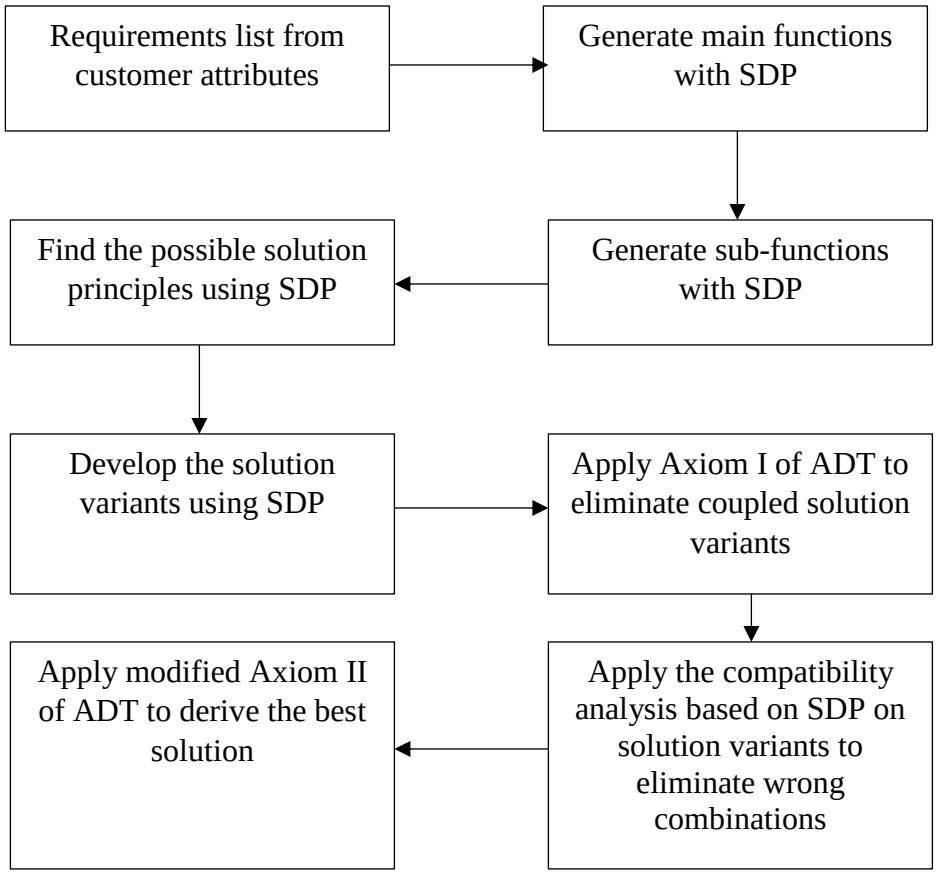


Figure 2.1 Integrated ADT-SDP approach (Muddada, 2014)

2.1.6 Design model

A design model represents the FR-DP relation. A design object model represents the DP (Zhang, 1994). A design requirement model represents the requirement of the customer as well as the technical specification (i.e., the requirement described in the technical terminology). A design process model represents how a design is conducted, including the decision-making processes (Zhang, 1994; Zhang, Lin, & Sinha, 2005; Lin & Zhang, 2004; Zhang & Wang, 2016). Further, a design process is divided into a general design process and a specific design process. The general

design process is suitable for all designs, but the specific design process is only meaningful to a specific design problem, e.g., four-bar linkage design (Zhang, 1994; Cao, Dolovich, Chen, & Zhang, 2018), rice mechanism design (Guo & Zhang, 2001), under-actuated robot design (Zhang, Zhang, & Gupta, 2018), etc. To a specific device design, both the general design process and specific design process are involved. This thesis takes the retractor design as a case throughout, discussion both the general design process and specific (i.e., retractor) design process. It may be clear from the above discussion that a design is the result of a design process.

Further, a model needs to be expressed with symbols that can be visually communicated among human designers. Examples of the visual expression of the model are textual expressions (both less formal and formal), and graphical expressions. Expressions need elements (visual or audial), synaptic rules and formats, like grammars in the human natural language, e.g., Chinese, English, etc.

In the design literature, the SDP has a set of graphic expressions for design, see Figure 2.2. In the ADT, **FR** represents the functional requirement, and **DP** represents the design product or solution. The correspondence between the set of FRs and the set of DPs can be expressed graphically in Figure 2.3. This graphical expression can be further expressed by the correspondence matrix, i.e. Equation (2.1):

$$A = \begin{bmatrix} A_{11} & A_{12} \\ A_{21} & A_{22} \end{bmatrix} \tag{2.1}$$

where A_{ij} characterizes the correspondence between FR_i and DP_j; in particular $A_{ij} = 0$ if there is no correspondence between FR_i and DP_j, on the other hand, $A_{ij} = 1$ if there is a correspondence between FR_i and DP_j.

Characteristic Input (I)/Output (0)	Generally valid functions	Symbols	Explanations
Type	Change	Generally valid functions	Type and outward form of I and O differ
Magnitude	Vary	Generally valid functions	I < O I >O
Number	Connect	Generally valid functions	Number of I > O Number of I < O
Place	Channel	Generally valid functions	Place of I ≠ O Place of I = O
Time	Store	Generally valid functions	Generally valid functions

Figure 2.2 Graphic expression of the general function *(Pahl, Beitz, & Feldhusen, 2007)*

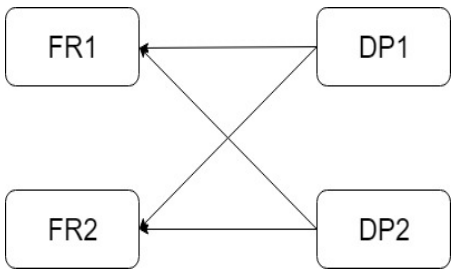


Figure 2.3 FRs-DPs correspondence

In the above, A is called a design matrix. When A is a diagonal matrix, the correspondence of the set of FRs and the set of DPs is shown in Figure 2.4a, and such a design is called uncoupled design. According to ADT-Axiom I, an uncoupled design is the best design. When A is a triangular matrix, the correspondence of the set of FRs and the set of DPs is shown in Figure 2.4b, and such a design is called decoupled design. A decoupled design means that the functional independence can be maintained if a design process follows a proper sequence, e.g., in the case of Figure 2.4b, the design sequence is DP1 —> DP2 (i.e., first design for FR1, followed by design for FR2). When A is neither a diagonal matrix nor a triangular matrix, the correspondence of the set of FRs and the set of DPs is shown in Figure 2.4c, and such a design is called a coupled design. According to ADT-Axiom I, the coupled design should not be pursued.

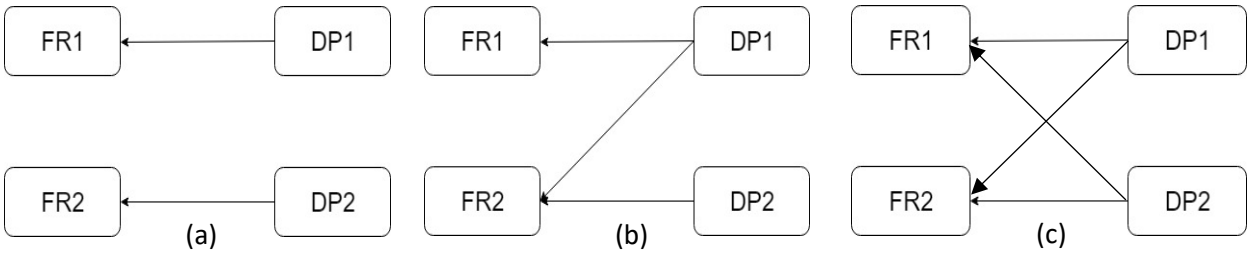


Figure 2.6 Three situations of the design

In Suh (2010), the correspondence in Figure 2.3 is expressed by an equation below

$$\begin{bmatrix} FR1 \\ FR2 \end{bmatrix} = \begin{bmatrix} A_{11} & A_{12} \\ A_{21} & A_{22} \end{bmatrix} \begin{bmatrix} DP1 \\ DP2 \end{bmatrix} \tag{2.2}$$

It is only recently noticed in Fan et al. (2015) that Equation (2.2) is misleading, as the equation (i.e., the right side is equal to the left side) is not based on any principles in physics and chemistry. Equation (2.2) cannot be used to perform any quantitative evaluation between FRs and DPs, e.g.,

calculating he value of FRs given the value of DPs. In fact, the sign "=" in Equation (2.2) does not mean to the mathematical operator "=" but represents "correspondence" between FRs and DPs.

2.1.7 Discussion

The brief overview of the state of arts in the general design theory and methodology in the above reveals that the contemporary general design process model is still weak in fulfilling its premise. Particularly, there are the following shortcomings identified with the general design process model: (1) The performance of a device under design, e.g., a robot device in design should walk at the speed of 10 meters per second, is of no way to be represented as well as expressed. (2) The constraint of a device under design plays its function is of no way to be represented as well as expressed. (3) There is no formal way to represent design options or device alternatives. (4) It is not clear about the role of the design phase theory in the general ADT-SDP design process. (5) The concepts of functions, such as the general function versus specific function and main function versus auxiliary function in the ADT-SDP, need to be further classified. (6) The function requirement decomposition needs a clearer guideline, e.g., whether the functional decomposition and device searching should be coupled, uncoupled or decoupled.

2.2 Design of soft devices

Devices are divided into two kinds: structure and mechanism. The structural device does not transfer motion but forces only. As such, the general function of a structural device is: to support a load and to clamp two pieces together. The mechanism device transfers both motion and force

(Zhang, 1994). Robots are beyond devices, as robots are expected to perform not only motion and force transfer but also learning and decision making and fulfilling different tasks in different environments (Chen et al., 2017). This thesis focuses on devices.

Soft devices can be defined as (1) not damaging their environment while they are performing their function and (2) performing their function based on their material deformation, adapted from the definition to soft robots by Chen et al. (2017). A partial soft device may include the connection (between two components) that allows a relative motion between two components. Usually, a device may be partially soft or called hybrid device (Cao, Dolovich, Chen, & Zhang, 2018; Cao, Dolovich, & Zhang, 2015; Cao, Dolovich, Schwab, L., & Zhang, 2015). Examples of the soft or partial soft device are soft claw gripper (Rateni, Cianchetti, Ciuti, Menciassi, & Laschi, 2015), partial soft robot hand (Noritsugu, Sasaki, & Takaiwa, 2002), and partial soft adaptable pavilion (Knippenberg, Habraken, & Teuffel, 2016).

One kind of the soft device has the following architecture: the device is built upon a piece of materials which are rationally shaped, and the device plays its function based on the deformation of the material. This kind of device may be called a compliant device (both compliant structure and compliant mechanism).

There is no general design theory and methodology available to the design of soft devices but compliant devices. The theory for designing compliant devices is the elasticity theory, and the methodology is based on the so-called module optimization. By the way, the methodology for analysis of a compliant device is the finite element method. In this thesis, the analysis of compliant devices is concerned.

2.3 Design of folding devices

Fu et al. (2015) defined the folding device as having two or more different states (particularly the shape) and enabling to switch from one state to another state on its own or on an external intervention. Further, at each state the device is locked. One of the best example of the folding device may refer to the foldable fan (Fig. 2.5). There are two states with the fan: collapsed state and expanded state (Fig. 2.5). An external torque is applied to the fan to execute the change of the states. The basic feature of the need to a folding device is that the space constraint for the device to play its function differs from the space constraint for transporting and storing the device. In this thesis, the folding device concept may be applied to the retractor design, as it seems that the initial state of the retractor significantly differs from its working state. Design of a folding device has two issues: (i) locking the device at the desired state and (ii) switching between the two desired states.

Collapsed fan

Expanded fan

Figure 2.9 The foldable fan

2.4 Medical protective devices

Medical protection devices are needed in surgery; they are expected to keep surgeons or assistants from unexpected accidents and/or to protect patients from potential injuries or infections. One example of such a device is the device of protecting spatter (U.S. Patent No. WO2009077695A3, 2009) in a surgical operation area, which is expected to limit the infection risks to patients. This device has a transparent film which is made of single-use sterile material. To maintain cleanliness and aseptic condition, the film is stored in the form of a coil at initial configuration. During use, the film will pass across the observation plate by extending the portion which is stored in a coil, to offer a bouncing sterile surface for the spatter of biological material from the operation area. In addition, it reduces the limitation of surgeons' visibility caused by wearing goggles, helmets, or some special display shields.

Another example is the pad (China Patent No. CN 201216601 Y, 2009), which is used to keep surgeons and assistants from X-ray exposure for minimally invasive surgery. The idea is to place a protective cushion on the surgical site which contains a cover case with a lead plate inside. There is another layer made of aluminum arranged between the lead plate and cover case, which is attached to each other by resin. There is a hole opened for the surgical requirement to operate the X-ray procedure. The advantage is that the pad is flexible enough to be placed on any sites such as thigh, abdomen, chest, and so on. It also efficiently protects doctors from the X-ray radiation, enabling nimble operation of the surgical procedure that could be impeded by wearing gloves. The vital point is that the material used in this pad gives easy access to sterilization, recycling and lower costs.

One more application is a disposable sterile protective cover (U.S. Patent No. US8011504B1, 2011), which is used in ophthalmology. This cover is made of a sterile and disposable material for multi-use. It is also biologically acceptable for contact with human eyes. Its purpose is to prevent the transfer of infection from patients to patients. There are a bunch of devices used for intraocular observation, diagnosis, treatment, etc. Since these devices are involved with the physical contact with patients' eyes, such covers could eliminate the sterilization and unexpected infection. The retractor concerned in this thesis is a kind of the medical protective devices.

2.5 Conclusion

In this chapter, the general design theory and methodology was briefly reviewed. Several salient points revealed in the discussion are revisited herein: (1) the concept of the general design theory and methodology versus the concept of the specific design theory and methodology were clarified; (2) six areas with the general design theory and methodology in the current literature were identified for clarification or improvement; (3) the concept of design model was clarified and observation that the literature misses a comprehensive design model was made. The chapter also summarized the concepts, including soft devices, folding devices, and medical protective devices, which are related to the design of the retractor concerned in this thesis. It can be seen from the discussion that the research objectives along with their scope, described in Chapter 1, warrant to be pursued.

CHAPTER 3

A NEW GENERAL DESIGN PROCESS MODEL

3.1 introduction

The six shortcomings were identified in the preceding chapter regarding general design theory and methodology (GDTM). They are re-visited here for the convenience of later discussions: (1) the performance of a device under design is no way to be explicitly represented; (2) the constraint of a device under design plays its function is no way to be explicitly represented; (3) there is no formal way to represent design options; (4) it is not clear about the role of the design phase theory in the general ADT-SDP design process model; (5) the concepts of functions, such as general function versus specific function and main function versus auxiliary function in the ADT-SDP, need to be further classified for their readily use; (6) the function requirement decomposition needs a clearer guideline. This chapter addresses these shortcomings. Specifically, Section 3.2 addresses the shortcomings (1)-(2) and (5)-(6). Section 3.3 addresses the shortcoming (4). Section 3.4 addresses the shortcoming (3) by proposing a formal representation of part of the design process. Section 3.5 illustrates how the design model works using an example. Finally, a conclusion is drawn (in Section 3.6).

3.2 Overcoming the shortcomings (1)-(2) and (5)-(6) in GDTM

3.2.1 Understanding the performance of a device

Neither in the ADT literature nor in the SDP literature, there is a clear definition of the performance. Indeed, only the concept of functional requirement (FR) is available in the literature, so a performance must be represented as a kind of FRs. For instance, for a walking robot, its function is: 'to walk', while the information 'speed of walking is 5 m/s' has nowhere to represent, as in the notation for FR, there is no syntax to express this piece of information. This thesis defines the performance as follows, adapted from Leonard (1999):

Definition 3.1: Performance. Performance is added upon a function, particularly specifying how well the function is performed in terms of quantity, quality, coverage, timeliness or readiness.

According to the above definition, the information 'speed of walking is 5 m/s' is a kind of performance information, specifically in terms of quantity.

3.2.2 Understanding the constraint requirement to a device

Neither in the ADT literature nor in the SDP literature, there is a concept called constraint. Though the concept of function seems to be clear (i.e., a function refers to a role the device under design plays), the fact that any function is performed under a condition or in context. This means that a device plays its function in a constraint manner, leading to the concept of constraint. This thesis defines the constraint as follows:

Definition 3.2: Constraint. Constraint is a condition or context under which a device plays its function. Constraint requirement (CR) is the required constraint.

The CR is further classified into the global CR and local CR. A global CR is applicable to a group of FRs, whereas a local CR is applicable to a specific FR. For instance, suppose that a brake pedal in a car must be in black colour. The black colour to the pedal is a local CR, i.e., this CR is only applicable to the pedal that is part of the brake function. The requirement that the total weight of a device should be less than 50 g is a global CR, as all the components of the device contribute to the total weight.

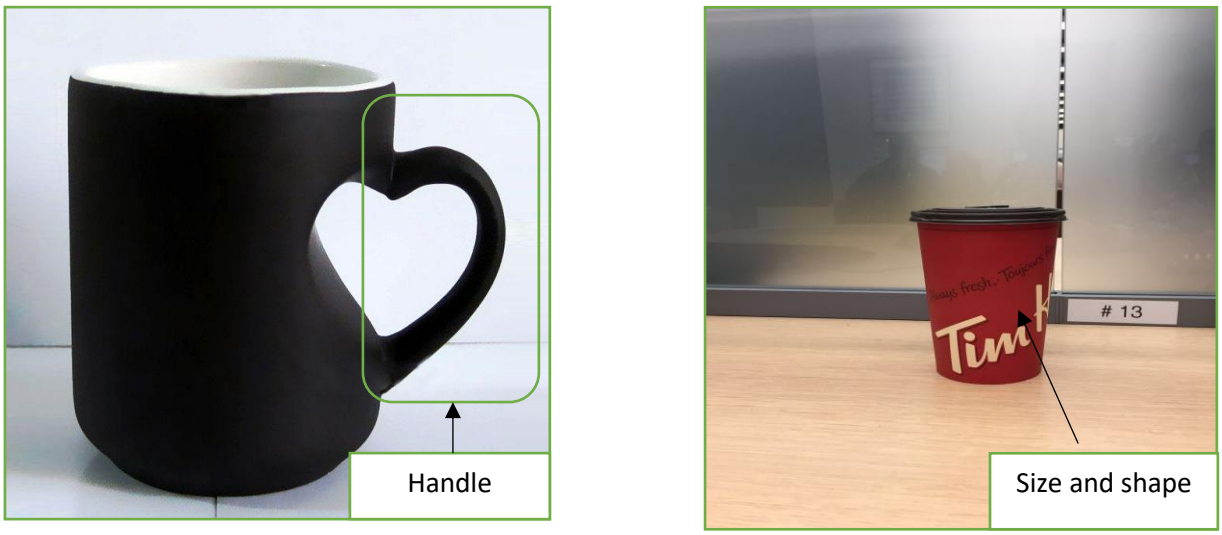
It is sometimes difficult to distinguish between a functional requirement and a constraint requirement. The following are several rules that help one distinguish FR and CR.

Rule 1: If a particular requirement concerns the usefulness of a device in a context, the requirement is a FR. Leonard (1999) further stated that the usefulness may be in one of the following aspects, such as quantity (how many), quality (how good), coverage (how large), time lines (how long), and availability (how often). In fact, Leonard (1999) usefulness refers to the performance as proposed in this thesis. If a requirement is about the factors that limit design flexibility, such as the environmental conditions or limits, the defence against internal or external threats, and the contract, customer or regulatory standards, it is a CR.

Rule 2: In the context of axiomatic design, Axiom I is not applied to the CRs, that is, CRs can be coupled to each other. For instance, the cost requirement for a design, say 'the total cost is less than 50 dollars', should not be defined as a FR, as otherwise the design is surely decoupled (all FRs are contributory to the total cost).

Example 1: design a device X that can hold hot water and can be grasped with a single hand of humans whose age is greater than 15.

Analysis: Applying Rule 1, FR1: 'hold water'; FR2: 'be grasped with a single hand'. There is a local CR to FR2, that is, 'age is greater than 15'. In this example 'with a single hand' may be considered as a FR or CR. The reason of defining it as a FR is that using a single hand to fulfill the function 'hold X' is a significant factor to be taken into consideration in the selection of device concepts in the subsequent design steps (i.e., conceptual design). Specifically, with the FR 'single hand', the design concept 'handle' (Fig. 3.1a) will be included as a design option in the subsequent design phase — conceptual design. However, if 'with a single hand' is considered as a CR, the design concept 'handle' may or may not be taken as a design portion, as the design concept 'size and shape' (Fig. 3.1b) may suffice to fulfill the FR 'being grasped' with the minimum effort.



(a) (b)

Figure 3.1 Illustration of FR and CR with the cup design

In summary, defining ‘with a single hand’ as a FR will likely come up with two design concepts: ‘handle’ and ‘size and shape’, while defining it as a CR may only come up with one design concept ‘size and shape’. It is noted that in design practice for the coffee cup, the design concept ‘size and shape’ is mostly taken, but defining ‘with a single hand’ as a FR or as a CR will move along different paths (but leading to the same result):

Path 1 (FR): propose two design options —> elaborate on which one is better —> the concept ‘size and shape’ is the final choice.

Path 2 (CR): propose one design option ‘size and shape’ —> the final choice.

It is noted that defining ‘with a single hand’ may also come up with two design options, i.e., Path 1 but the likelihood is lower than defining ‘with a single hand’ as a CR. Nevertheless, it can be seen from the above discussion that defining a requirement as a FR or CR is not of a crystal decision, which is reflective of the nature of design — that is design is mix of sciences (objectivity) and arts (subjectivity).

3.2.3 Ontology of functions

In SDP (Pahl, Beitz, & Feldhusen, 2007), the notions of main function and auxiliary function are introduced without a much clear definition. There is no objective criterion to determine whether a function should be considered as a main function or an auxiliary function. This thesis attempts to give the following clarification.

(1) Main function versus auxiliary function

The main function of a system is one that uniquely represents the machine system in terms of its usefulness; in other words, if this function is missed, the system will be a different one. To the example used in the text of Pahl, Beitz, & Feldhusen (2007), 'carpet tile packing', the function 'remove offcut' is not a main function, as the absence of it does not change the overall function of the machine system, namely 'packing carpet tile'. Details of this example are also put in Appendix A for the reader's convenience. The auxiliary function is one that provides an additional, a supplementary, or helpful function to the main function, making the overall function be played better. To the foregoing example, the function 'remove offcut' is an auxiliary function to the main function 'separate carpet tiles from offcuts'.

The distinction of the two concepts (main function and auxiliary function) is significant to having the machine with the benefits including a clear operation logic, clear division of tasks over the human and machine, and high degree of modularization of the machine system. For instance, if the 'removal of offcuts' is not included in the function decomposition lattice, this function may need to be fulfilled by the human operator, defining the degree of automation with the carpet tile packaging machine. These benefits will further help to improve the performance of product design, manufacturing and management.

(2) General function versus specific function

The concepts of general function and specific function are very important concepts in SDP (Krumhauer, 1974; Pahl, Beitz, & Feldhusen, 2007). In this literature, the general function is defined as a generally valid function, while the specific function is defined as a function in

connection to a specific task. This definition is, however, not easy to be taken in practice. In the following, some modification to this definition is discussed.

The goal of any system can be generally viewed as transferring Substance A to another Substance B. There are three types of substances: energy, physical entity (material), and conceptual entity (information or knowledge). The general function operates on the general types of substances to change their characteristics. There are five characteristics for the general types of substances according to SDP (Krumhauer, 1974; Pahl, Beitz, & Feldhusen, 2007): *type*, *quantity or magnitude*, *number of objects*, *place*, and *time*. There are five types of the change operation upon these characteristics of substances: *convert* (characteristics: type), *vary* (characteristic: quantity or magnitude), *connect* (characteristic: number of objects), *move* (characteristic: place), and *store* (characteristic: time). A general device is nothing but to change a general substance from its input state to its output state. A specific type of substance refers to a specific material with a specific energy or a specific piece of information. A specific device refers to a device that fulfills a specific task. In fact, the general function and the specific function corresponds to the generalization and specialization relation; particularly, any specific function can be generalized to one of the five types of change in the general function. For example, in carpet tiles packing (Appendix A), the specific function ‘separate offcuts’ can be generalized to the general function ‘connect number of objects (from a fewer number of objects to a greater number of objects’).

3.2.4 Function Decomposition and Zig-zag Process

Given a required overall function along with constraints, one may need to decompose it into a series of simpler functions along with constrains, FR1, FR2 (only two simpler functions without the loss of generality). There is no guideline in literature about how such decomposition can be carried out. To a processing system, e.g., the carpet tile packing machine (Appendix A), one may decompose an overall function into a series of functions by following the processing order of the machine. This thesis proposed the following guideline for the function decomposition to a processing machine:

*Axiom for the function decomposition for the processing machine axiom (**FD-Axiom I**)*: to decompose the overall function of a processing machine based on the processing order.

Remark 3.1: the overall function and its sub-functions follow the data relativity principle (Zhang, 1994), that is, a function of one overall function may be an overall function of other functions when it is decomposed.

Remark 3.2: with an overall function being decomposed, its constraint is also decomposed.

Remark 3.3: both manufacturing and service systems are a kind of processing machines (Wang et al., 2016).

To the system or device that all its components simultaneously contribute to an overall function, e.g., a coffee cup, a manipulator, etc., the first is to consider design (i.e., to find a device to meet a function in a context) as a problem solving and then function decomposition becomes the problem

decomposition — i.e., to decompose a complex problem into a series of simple problems. For the convenience of later discussions, such a system is called integral system. This thesis proposes the following guideline for the function decomposition to an integral system:

*Axiom for the function decomposition for the integral system (**FD-axiom II**)*: to decompose the overall function of an integral system based on problem decomposition — complex one to simple one.

Remark 3.4: In design literature, there is a so-called zig-zag process (Suh, 2010). In general, the zig-zag process involves two domains: DP domain and FR domain. Zig-zag means that the cognitive or design process goes along two lines: Line 1 (in the FR domain): Decomposing FR into FR1, FR2; Line 2 (in the DP domain): Discovering DP (i.e., DP1 for FR1, DP2 for FR2). In case that no DP can be found for a FR (e.g., FR1), that FR (i.e., FR1) is further decomposed into FR1.1, FR1.2, …. (The design process goes along Line 1), and subsequently the design process will go along with Line 2 (i.e., the DP domain). This zig-zag (Line 1 – Line 2) process will go on until all FRs get DPs. The foregoing zig-zag process assumes that FRs and DPs satisfy Axiom I of ADT, that is, each DPi (DPj) only affects FRi (FRj) but not FRj (FRi). Otherwise, the design process goes as follows: If for a FR (say FR1), DP1 affects not only FR1 but also FR2, then FR2' is formed, FR2' is the original FR2 subtracted by the function fulfilled by DP1. Subsequently, seek DP2' for FR2' rather than FR2. This process is in fact a decoupled design process in ADT (Suh, 1990).

3.2.5 Function independency evaluation

It is possible that a design process comes up with a design shown in Fig. 3.2, in which FR1 is further decomposed into two function requirements, namely FR1.1, FR1.2, and subsequently, DP1.1 and DP1.2. It can be seen from Fig. 3.2, at the first level of function hierarchy, there are three sub-function requirements, FR1, FR2, FR3, and except FR1, FR2 and FR 3 get DP, namely DP2, DP3. At the second level, there are DP1.1 and DP1.2. DP1 is aggregated from DP1.1 and DP1.2. It is noted that aggregation differs from assembly; aggregation may result in a DP which has the behavior beyond a simple summation of its member DPs, while assembly is a simple summation of its member DPs, hence, assembly is a special case of aggregation.

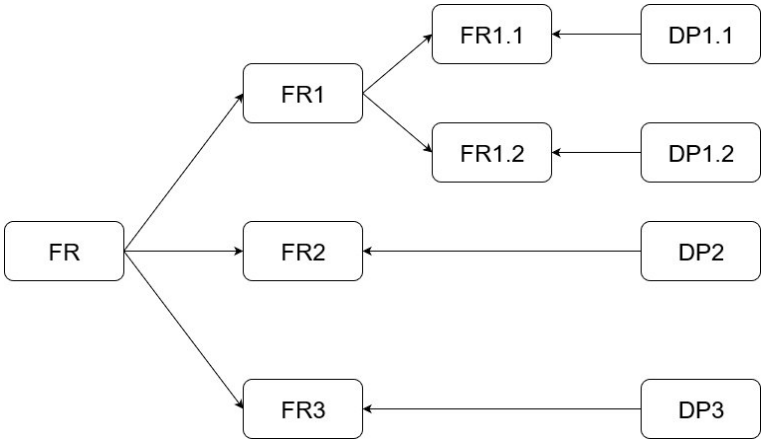


Figure 3.2 Design levels

The evaluation of a design may have two ways. The first way is to evaluate design level by level, that is, to the design of Fig. 3.2, the evaluation takes place on Level 1 on DP1 (aggregated from DP1.1 and DP1.2), DP2, DP3, and Level 2 on DP1.1 and DP1.2. The second way is to evaluate design on all the DPs at the end node of the DP hierarchy (Fig. 3.2 right), that is the evaluation takes place on DP1.1, DP1.2, DP2, and DP3. In principle, the second method is more accurate than

the first method, as the first method creates a local scope for DP1 (FR1) but DP1.1 and DP1.2 may affect DP2, DP3 on their own right, which may differ from the effect of DP1 (aggregated from DP1.1 and DP1.2) on DP2 and DP3, respectively.

3.3 A general design process model

The general process model is based on FCBPSS (Lin & Zhang, 2004; Zhang, Lin, & Sinha, 2005; Zhang & Wang, 2016; Zhang et al., 2005; Zhang & Wang, 2016), which is in Appendix B for the convenience of readers. Fig. 3.3 shows a diagrammatic representation of the FCBPSS-based general design process. It shows:

(1) A design begins to transform the customer's voice of the need of a product to the technical specification of the need, namely the description of the need in technical terminology (Fig. 3.3a). The former description of the need is usually imprecise, which could be vague, uncertain, and/or missing (Cai, Lin, Han, Liu, & Zhang, 2017), while the latter description is precise. The technical specification includes function requirement, performance requirement, and constraint requirement.

(2) After the technical specification is made, the concept or conceptual design starts (Fig. 3.3a). The concept design includes (Fig. 3.3b): (i) decomposition of FRs along with performance requirement and constraint requirement and (ii) finding of DPs, a process runs in a zig-zag manner. It is noted that the DPs here is description of concepts or working principles of the device under design. Fig. 3.3b shows steps to conduct function decomposition and finding of DPs. Specifically, function decomposition follows the FD-axiom as discussed previously. Finding of DP follows finding its general function for each specific function and searching design database with the

general function to generate all matched past designs, retrieving the past designs, comparing the specific functions along with performances and constraints with the required specific functions, performances and constraints to lead a set of DP options.

(3) After the conceptual design is done, the analysis of the set of DPs options is carried out to generate the actual behavior (AB) along with the actual property (AP) of DPs options.

(4) Evaluation is carried out by comparing the actual behavior and property with the required behavior and constraint as well as by checking DPs options with ADT-Axiom I if a design is at the concept design phase.

(5) Evaluation is also carried out by ADT-Axiom II if the information is enough if the design information is enough.

(6) Evaluation is also carried out by SDP physical compatibility analysis if a design is at the embodiment design phase.

Remark 3.5: The design process in Fig. 3.3 is applicable to all three design phases (concept design, embodiment design, and detail design). In the case of embodiment design, the resulting DP out of the conceptual design, denoted as C-DP, serves as a constraint at the embodiment design phase and the FR as well as CR in conceptual design, denoted as C-FR and C-CR, will be inherited to the embodiment design phase.

Remark 3.6: C-FR along with C-CR may be further decomposed, particularly along with its performances, and so forth for embodiment and detail design (if needed). That is to say, the zig-zag process is valid to both concept design and embodiment design, and within one design phase, there may be more than one layer of function decomposition.

Remark 3.7: The borderline between concept design and embodiment design is that in the embodiment design phase, the concern is about material selection, material distribution, structural layout, and sizing, while in the concept design phase, the concern is about working principles, physics or laws that govern the behavior of a device under design.

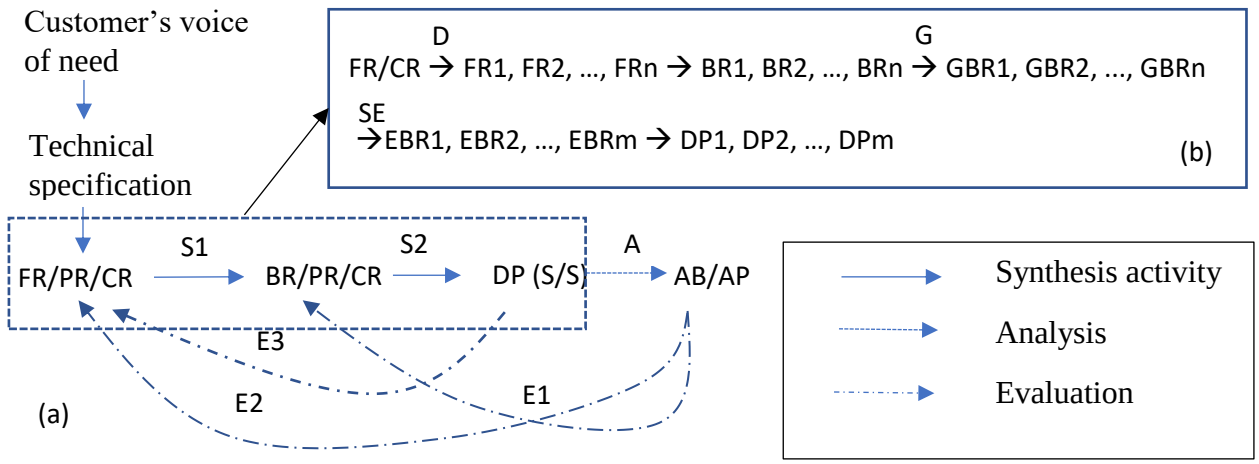


Figure 3.3 FCBPSS-based general design process (S: synthesis, E: evaluation, A: analysis, S/S: state/structure, AB: actual behavior, AP: actual performance, SE: search, D: decomposition G: generalization)

3.4 Towards a Formal Approach to Design Process Representation

In this section, a relatively formal approach is presented for design process. In fact, to a model, there are always two aspects: (1) constructs that capture the semantics of a domain of discourse,

and (2) a tool to represent the constructs. To a general design process, the constructs are FR, DP, etc., including their relationships, as discussed above. In this section, a tool to represent them is discussed.

3.4.1 Notation for the representation of the decomposition of FR and DP

A notation was developed for representing the function decomposition in the following:

Notation 1: FR.i.j.m, as shown in Fig. 3.4, where i, j, m = 1, 2, 3, …

In Notation 1, the number of dots '.' represents the number of levels. It is further noted that the dot '.' for Level 1 is usually omitted. Therefore, FR1 and FR2 stand for the 1st function at Level 1 and 2nd function at Level 1. The notation also represents the historical information of decomposition. For instance, FR1.2.1 stands for the 1st function at Level 3 along with the history of decomposition (i.e., the parent function of FR1.2.1 is FR1.2, which represents the second function at Level 2, and the parent function of FR1.2 is FR1, which represents the first function at Level 1).

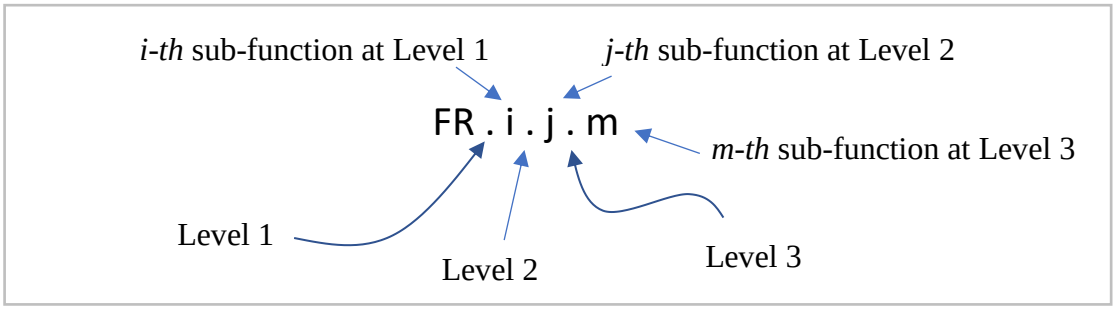


Figure 3.4 The definition of FR along with its decomposition

Fig. 3.5 shows an example of the function requirement decomposition. The notation of DPs follows that of FRs. That is, DP1.2 means a design solution to FR1.2. To DP, there may be several alternatives, and this can be represented by DP.i.j[a], where 'a' denotes an alternative design. For instance, DP1.2a and DP1.2b stand for two design alternatives to FR1.2.

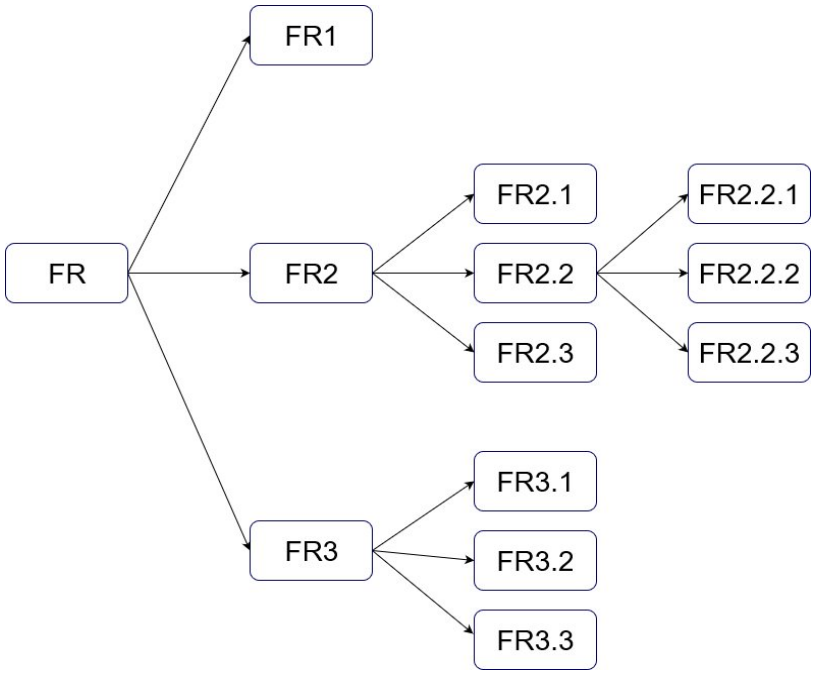


Figure 3.5 Representation of function requirement decomposition

3.4.2 Notation for the representation of the performance requirement (PR)

A notation was developed for representing PR as follows:

Notation 2: FR {PR-ID/name/expression}.

In Notation 2, ID means identity follows Notation 1, where ‘name’ gives the name of a specific performance, and ‘expression’ gives a mathematical expression. For instance, FR is ‘walking’; FR {PR-1/speed/5 m/s} means: the speed of walking is a performance associated with ‘walking’, and ‘the speed is 5 m/s’. FR {PR-2/stability/lateral swing angle <1 degree} means: the stability is another performance associated with ‘walking’, and its lateral swing angle (which represents the stability) should be less than 1 degree. In this example, one FR can have more than one performance requirement. Fulfillment of two performance requirements will be achieved with the information beyond the concept, including the material and size, both of which are only available in embodiment design. The discussion thus far implies that concept design focuses on FR but not PR, and ADT-Axiom I makes sense to the concept design only (see the previous discussion as well).

3.4.3 Notation for the representation of the constraint requirement

A notation was developed for CRs as follows:

Notation 3: CRi (list of FRs or name of a system): expression, where i = 1, 2, …

In Notation 2, the parenthesis '(…)’ gives the scope where a CR applies. For instance, FR1 is ‘walking’. Suppose that the function ‘walking’ is on an ice road. The phrase ‘on an ice road’ is a constraint (i.e., a condition under which the function ‘walking’ is performed). This CR can be expressed by Notation 3 as: CR1 (FR1): ‘on ice road’.

3.5 Illustration -- Design of a Clamp System

At the agriculture cafeteria in the University of Saskatchewan, there is a stack of cups for customers to fill with drinks (Fig. 3.6). In the following, the design of this system is used to illustrate how the above design model works.

Figure 3.6 Cup Clamper

There are two function requirements with this device: (1) to store a group of cups with the same size (FR1), (2) to store cups of different sizes (FR2), (3) to be ready for a user to pick up one cup (FR3), and (4) to release one cup by the pulling action from a user (FR4). The function requirements (FRs) can be represented as:

FR1 {PR-1|Number of cups|> 20 cups}.

FR2 {PR-1|Size range| 2 - 3 inch at the large end of the cup}.

FR3 {PR-1|Opening diameter| 1.5-2.5 inch at the small end of the cup}

FR4 {PR-1|number|1 cup}.

At the concept design phase, C-DP1 (where C stands for concept) is ‘elastic deformation/friction’, meaning that a device that fulfills this function is based on the elastic deformation (Fig. 3.6). C-DP2 is ‘adjusting the pressure imposed from the elastic strip to the cup’ (Fig. 3.6; see the elastic strip). C-DP3 is ‘opening’, i.e., the cup is open to the user to access. C-DP4 is ‘pulling force’. There are a couple of remarks concerning this design in the following: Fig. 3.7 brings together all the DPs.

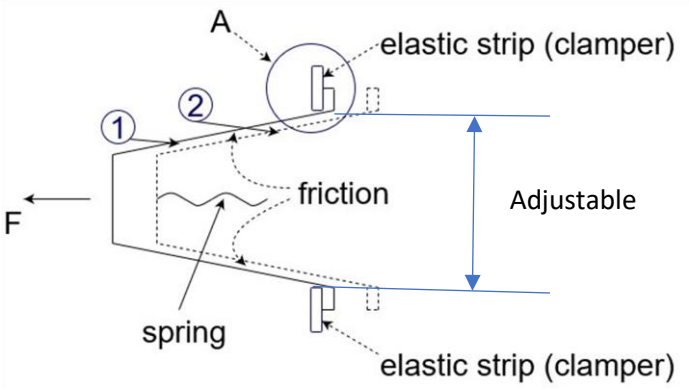


Figure 3.7 The Work Principle of Cups Stack

Remark 3.8: FR4 is completed by a human user, a process means that the whole system is a human-machine system.

Remark 3.9: In fact, there is another human operation, that is, the maintenance personnel needs to press the cups into the storage. But this function is de-associated with all the other functions. That is to say, the user’s operation of this function will not affect the rest of design.

Remark 3.10: The operation has a sequence with this device, that is, first FR1 and then FR4.

Fig. 3.8 shows the correspondence between the FRs and DPs. Clearly, the design for FR1 and FR4 is a decoupled design. Notice Remark 3 above, the coupling of the design in this case can be decoupled by following this sequence; the user's operation (FR4) is the end of point to decouple the design. The design then meets ADT-Axiom I.

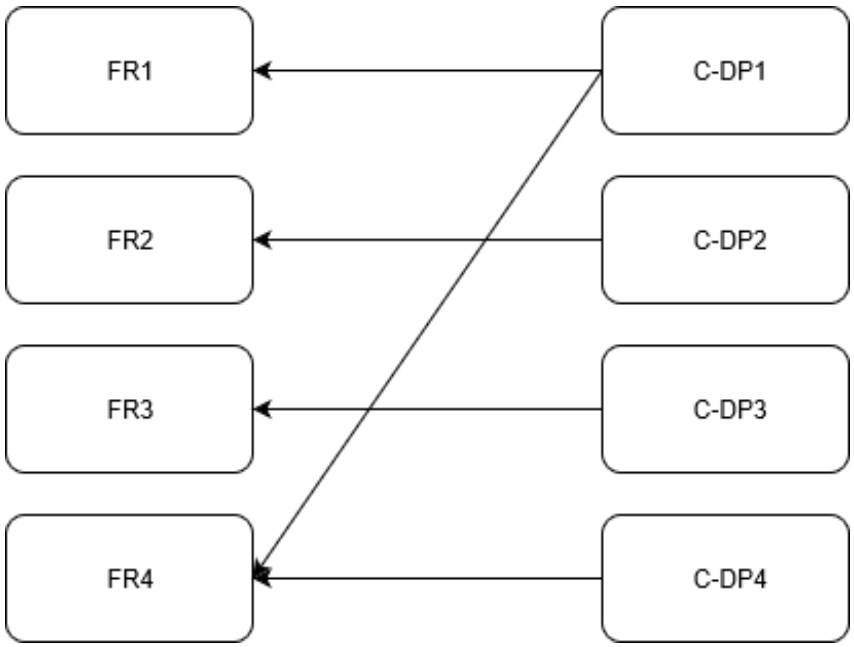


Figure 3.8 FRs-DPs relation

Given the fact that the whole system is a human-machine system, the DP4 (i.e., the user's operation 'pulling') needs to be described so that the role of decoupling as well as the achievement of the FR4 can be played. In this case, this pulling operation should be acted in a slow procedure, otherwise, more than one cup may be pulled. Nevertheless, how slow the user's operation should depend on the friction force (pressure) and elasticity in the system, both factors are the business of embodiment design.

There may be some other design options to achieve the FRs, e.g., for the FR1. Fig. 3.9 shows three other design options for the FR1. Let us denote the C-DP1 as discussed above C-DP1a. The other three C-DP1s are thus C-DP1b, C-DP1c, and C-DP1d. C-DP1b is 'gravity', which means the principle of device for fulfill the storage is based on the gravitational force, see Fig. 3.9A; C-DP1c is 'vertically elastic element (spring)' clamper, which means that the stack storage of cups is based on the vertically elastic pressing, see Fig. 3.9B; C-DP1d is 'horizontally elastic element (spring) clamper'; see Fig. 3.9C. Once more than design options are available, the evaluation of selecting the best one needs to be conducted according to Fig. 3.3. Due to the sake of illustrating the effectiveness of the proposed notation, the discussion of this example stops here.

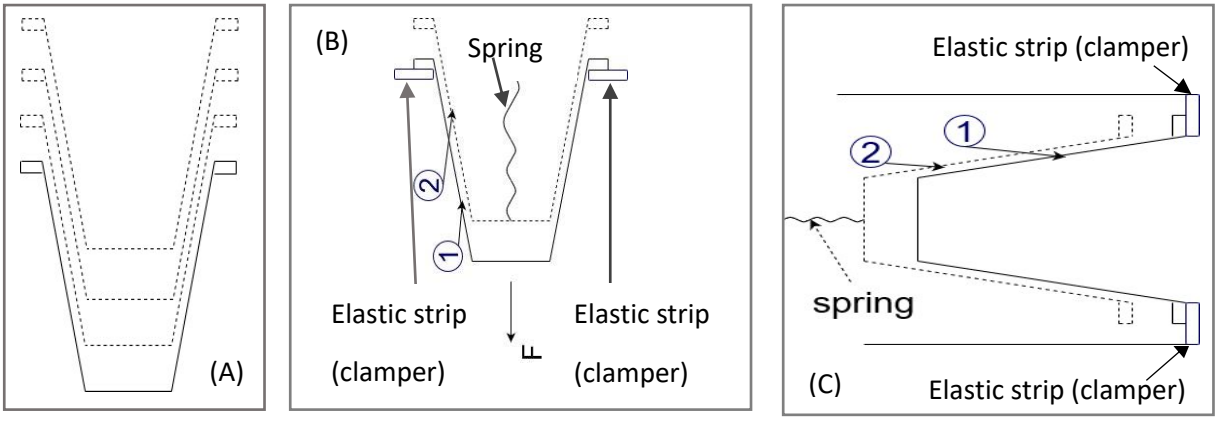


Figure 3.9 Schematic Diagram of Different Design Parameter

3.6 Conclusion

This chapter addressed several controversial issues presented in the existing general design theory and methodology and proposed a more formal general design process model (Fig. 3.3) and a more formal notation for representing a design. An example was discussed to show how the proposed notation works. It can be concluded that with the proposed notation, a design can be conducted in

a more formal and systematic way, which may open a new avenue in future development of the so-called “machine designing”, i.e., design is conducted by a machine (computer). The notion of machine designing may be in parallel with the notion of machine learning.

CHAPTER 4

THE REQUIREMENT FOR THE RETRACTOR

4.1 Introduction

In this chapter, the requirement for the retractor is presented in detail. This includes a detailed discussion of the application problem, i.e., open body surgery for hernia repair, from which the requirement from the medical side is derived (in Section 4.2). In Section 4.3, the requirement from the technical side, also called technical specification (Zhang, 1994; Zhang, 2018), is derived by using the improved design theory and methodology along with the notation for representing a design, developed in Chapter 3. There is a summary at the end of this chapter.

4.2 Open surgery for hernia repair

The overall open surgery for hernia repair was discussed in Section 1.1. Here more details about it are presented to help derive the requirements for the retractor design. The operation for hernia repair can be described in the following steps:

Step 1: Make an incision at the hernia area in the abdominal wall and find the hernia area (Fig. 4.1). The size of the incision should be made as small as possible.

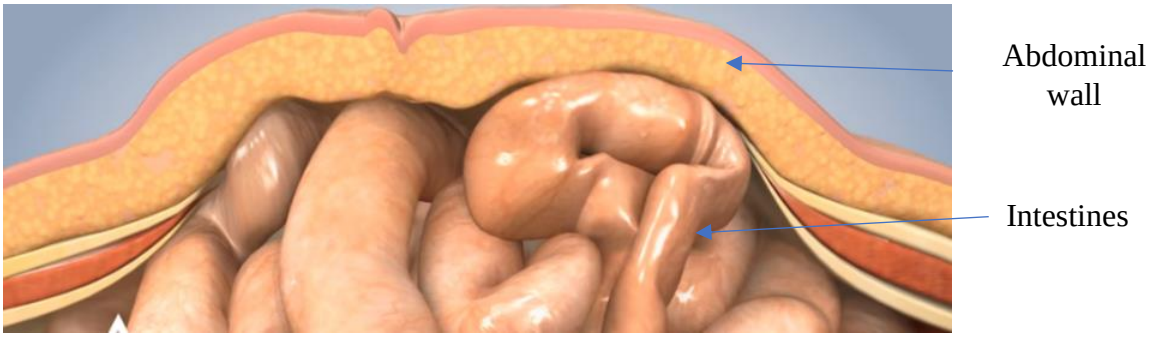


Figure 4.1 Step 1 of the Open Surgical Process

Step 2: Separate the intestine from the hernia which is attached with the inner wall of the abdomen (Fig. 4.2). Then, place a mesh patch between the abdominal wall and the intestine (Fig. 4.3). The mesh is made of the synthetic materials or animal tissues (U.S Food & Drug Administration, 2018), and it is soft and easy to be manipulated into the place.

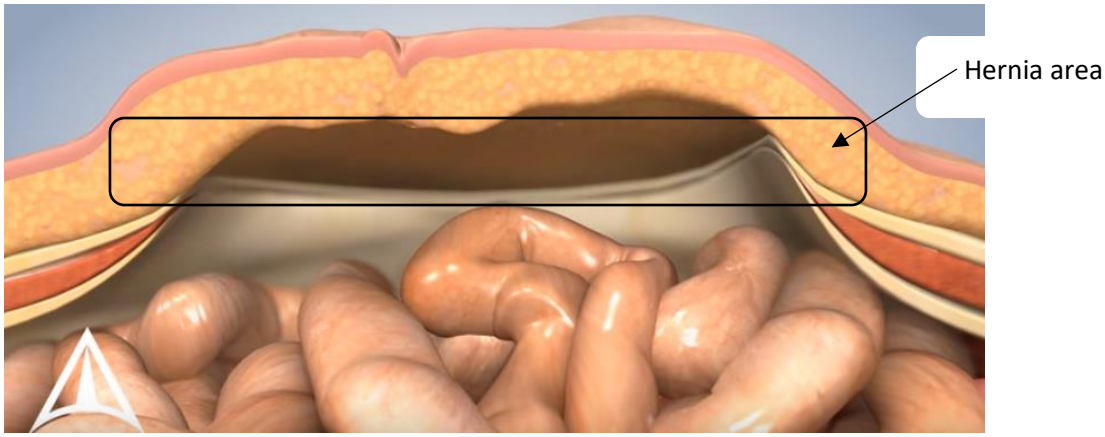


Figure 4.2 Step 2 of the Surgical Process

Step 3: Stitch the mesh to the inner wall of the abdomen (Fig. 4.3). During the stitching process, the suture passer may accidently touch and hurt the intestine (Fig. 4.4). Therefore, a spatula (the current practice) or a retractor (future pending the development of it in this thesis) is placed on the intestine to avoid the suture passer touching the intestine. The retractor must completely cover the area of intestine. It is noted that the small intestine is about 2.5-3 cm in diameter in adults (Small intestine, 2018).

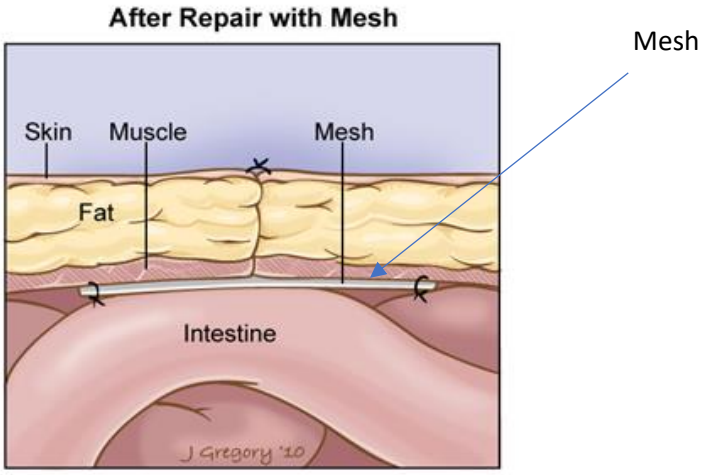


Figure 4.3 Step 3 of Surgical Process

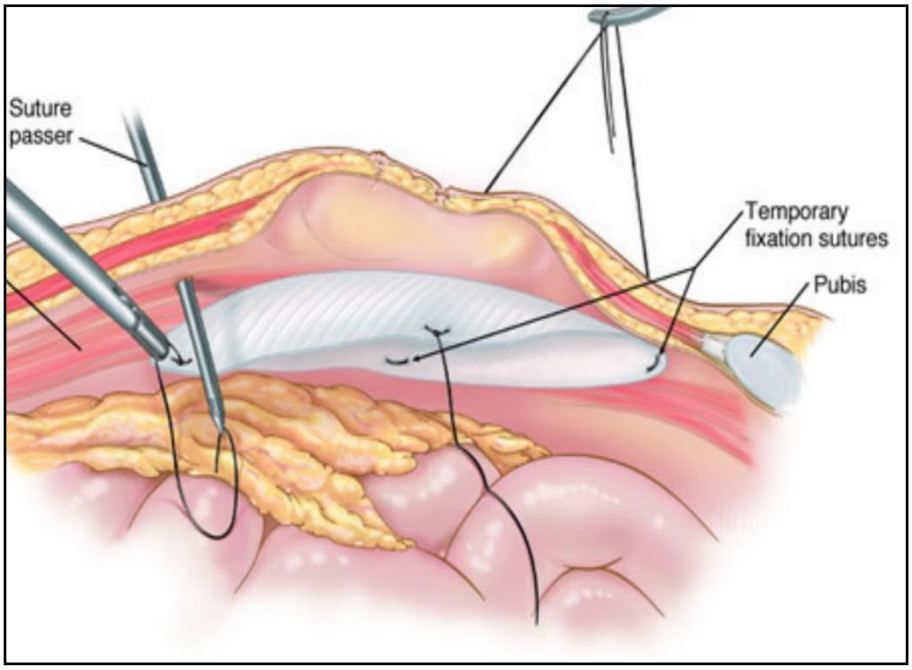


Figure 4.4 Stitching process

4.3 Luo's prototype

The current practice in the hernia repair surgery is to use the device called spatula which is placed on the top of the intestine to avoid the suture passer to touch the intestine, as illustrated before in Chapter 1 with Fig. 1.4 and Fig. 1.5. The main problem with the spatula is that for each stitching, the spatula needs to be repositioned, a procedure which is extremely time consuming. Luo's prototype of the retractor nicely addressed this problem with the design concept of folding / unfolding (or retractor) such that when the retractor is placed on the top of intestine, it is unfolded or expanded to cover the whole area of the concerned intestine. As such, one only needs to deploy the retractor once on the top of the intestine for all the stitches. The material of Luo's prototype is vinyl, which is stiff enough to prevent the intestine tissue from any movements to prevent small

intestine from squeezing out of the retractor. However, Luo's prototype has the following drawbacks:

(1) The material is not biocompatible according to the U.S. Food & Drug Administration.

(2) The plates may move relatively, implying that there may be clearance between plates so that the small intestine may sneak out from the retractor.

4.4 The technical specification for the retractor

The technical specification, a designer-oriented description of the requirement for a device (Zhang, 2018), is presented in the following. The overall function requirement (**FR**) of the retractor is: to facilitate the open surgery for hernia repair especially in the mesh stitching process. This FR is divided into several sub-functions, which are described below:

- FR1: Be inserted into the abdominal cavity.
- FR2: Be resistant to the puncture of the suture passer.
- FR3: Be able to cover the whole surgery area.

To each FR, there may be several performance requirements (PRs) and constraint requirements (CRs). To FR1, the cavity is characterized by a cuboid space (Fig. 4.5), in which the length (L) is about 30 cm, the width (W) is 30 cm, and the height (H) is about 15 mm. This piece of requirement is better defined as a constraint requirement to FR1. To FR2, the maximum pressure the retractor is subject to should be less than 18 MPa (in Chapter 5). This piece of requirement is better defined as a performance requirement to FR2. To FR3, first, it should be a seamless coverage (i.e., no small intestine, which has the dimeter of 2.5-3 cm, can squeeze out of the retractor), second, the coverage area is about 300 cm^2, and third, the unfolded state of the retractor must be stable in the

sense that the plate must stay in their positions with the range of tolerance being no more than 2.5-3 cm after the retractor is expanded. This piece of requirement is better defined as a performance requirement to FR3.

There are two overall constraints to the retractor, namely the retractor must be biocompatible (CR4) and soft (CR5). To CR4, it means the compliance of US FDA (ISO 10993-1, 2016) in the areas of cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility, and mamateriallyediated pyrogen testing. To CR5, the definition of softness in Chen et al. (2017) was taken, that is the retractor should not create the stress in the intestine larger than the allowable stress otherwise the stress will damage the tissue. The tensile stress of the intestine is 1.289 MPa according to Egorov et al. (2002).

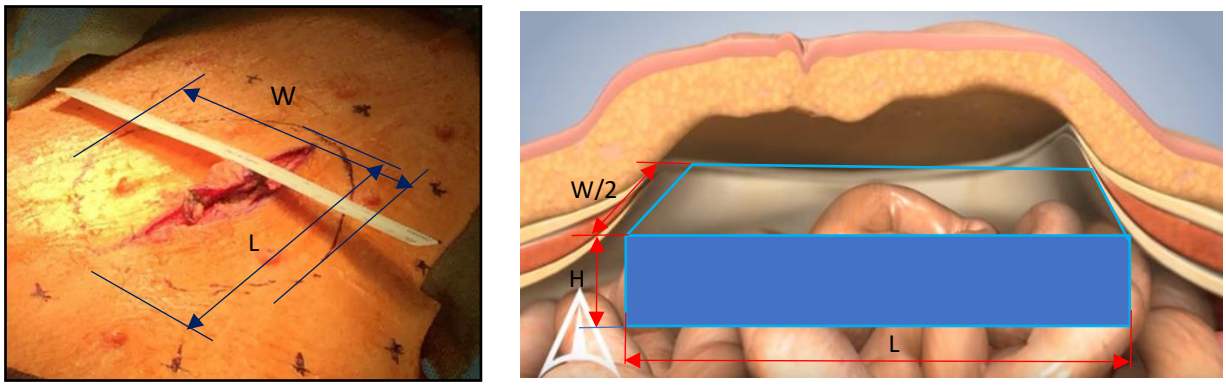


Figure 4.5 Cuboid space cavity

By applying the notation proposed in Chapter 3, the technical specification for the retractor is presented as follows:

- CR1 (FR1): the length of the retractor in the collapsed state is less than 15 cm.
- FR2 {PR-1|Strength of the material|> 18 MPa}.

- FR3 {PR-1|Coverage gap|<2.5 cm;

  PR-2|Coverage area|>300 cm^2;

  PR-3|Dispositioning|<2.5 cm}.
- CR2 (FR3): Volume of the expended state of the retractor is: L<30 cm;

  W<30 cm, H<1.5cm.
- CR3 (FR1-FR3): conformity with the US FDA (ISO 10993-1, 2016) in the aspects of cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility, and mamateriallyediated pyrogen testing.
- CR4 (FR1-FR3): the maximum stress on the intestine tissue should be less than the tensile strength of the intestine tissue.

Remark 4.1: Regarding CR1 (FR1), the total length of the incision is less than 30 cm (Fig. 1.6). The length of the folded retractor is therefore less than 15 cm.

Remark 4.2: Regarding PR-1 of FR2, the tensile strength of the material should be higher than 18 MPa in order to resist the passer based on the experiment (Appendix C).

Remark 4.3: Regarding PR-1 of FR3, coverage gap measures the degree of seamless in coverage. Since the smallest intestine is about 2.5 cm, so the degree of seamless in coverage should be smaller than 2.5 cm so that the intestine tissue cannot be squeezed out of the retractor. Further, this concern came from the experience of Luo's prototype.

4.5 Summary

This chapter presented a formal representation of the technical specification for the retractor. The technical specification. By applying Axiom I of ADT to the function requirements, one can see that the FRs are independent to one another except that FR1 and FR3 have an inherent conflict relation in terms of space (the two are related to the space of the body) but they are independent in terms of time (the two play their roles at different times).

CHAPTER 5

DESIGN AND ANALYSIS

5.1 Introduction

This chapter presents the design of the new retractor. Specifically, the general design process summarized in Chapter 2 and improved in Chapter 3, together with some specific design process, was followed. Section 5.2 presents design. Analysis of the design based on the finite element simulation is also presented (in Section 5.3). A conclusion is given in Section 5.4.

5.2 Design

5.2.1 Conceptual design

According to the general design process of Fig. 3.3, the following steps were taken.

Step 1: Developing the technical specification for the retractor.

This has been completed in Chapter 4 (see Section 4.4).

Step 2: Concept design

According to the technical specification as developed in Chapter 4, deign concepts for FR1, FR2, and FR3 need to be found otherwise FRs need to be modified (see Fig. 3.3). Before the design steps move on, a note is taken that in the execution of the general design process as described in Fig. 3.3, design of the retractor directly went on to find DPs from FRs with PRs and CRs (i.e., omitting the step of behavior design), because the retractor is a single device rather than a process of several steps (i.e., the process machinery).

To FR1, FR2, and FR3, respectively, design parameters (DPs) were proposed as follows:

- DP1: shape & geometry (meaning the retractor should be structured on shape and geometry).
- DP2: material (meaning that the retractor should be constructed by selecting a right material in order to meet FR2).
- DP3: a mechanism as shown in Fig. 5.1 (meaning that several components constructed based on DP1, named **plates** hereafter, are connected by a revolute joint and driven to perform a relative rotation to be expanded, as shown in Fig. 5.1).

It can be concluded that the above design meets the ADT-Axiom I, as the DP – FR correspondence relation can be described by Fig. 5.2.

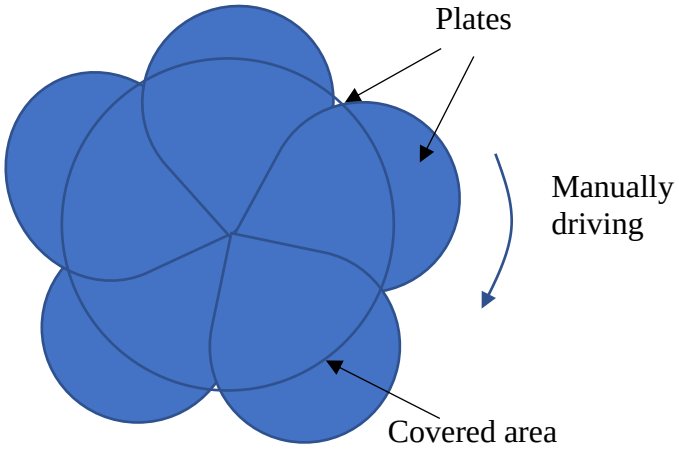


Figure 5.1 DP3 mechanism

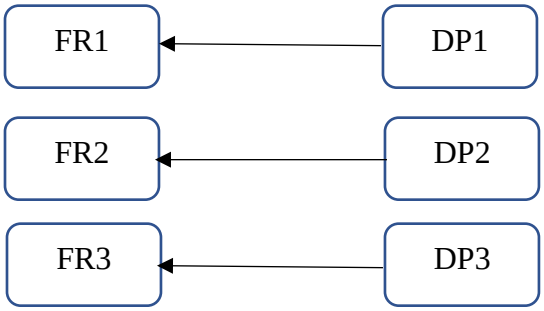


Figure 5.2 FR – DP relations

Note that an alternative design may be the one shown below:

DP1a: shape & geometry, so the same as DP1.

DP2a: material, so the same as DP2.

DP3a = DP1a.

In this case, the design is a coupled design, in which DP1a corresponds to two FRs (see Fig. 5.3).

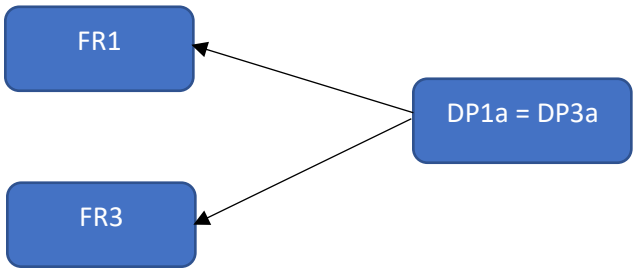


Figure 5.3 The coupled alternative design

As mentioned before in Remark 4.4 of Chapter 4, FR1 and FR3 are in conflict. That is, to FR1, the design is in favor of a small shape (i.e., reducing the size of incision) but to FR3, the design is in favor of a large shape (i.e., covering the affected intestine completely). In this case, there may be a design (DP1a*) that can meet these two conflicting goals, but such a design is likely with a poor robustness (Zhang & Luttervelt, 2011). Therefore, this alternative design was rejected. It is further noted that combination of DP1 and DP3 leads to the concept of the folding device or mechanism (see the previous discussion in Section 2.3). So, specific design knowledge for folding mechanisms was followed in the subsequent design process.

Now let us look at the performance requirement of the FRs. To FR1, the performance requirement was further addressed at the embodiment design phase, which will be discussed later in this chapter. To FR2, there is one performance requirement, and it will be addressed in the embodiment design phase. To FR3, there are three performance requirements. FR3 is further decomposed into:

- FR3.1: gap coverage (refers to PR1 of FR3).
- FR3.2: overall coverage (refers to PR2 of FR3).
- FR3.3: locking (refers to PR3 of FR3).

FR3.3 can be further decomposed into:

- FR3.3.1: locking of individual plates with respect to the global locking after the retractor is expanded.
- FR3.3.2 global locking after the retractor is expanded (a necessary requirement for any folding mechanism; see the previous discussion of Section 2.3 of Chapter 2).

DPs were developed for FR3.1 to FR3.3 and are described as follows:

- DP3.1: the origami sheet (see Fig 5.4).
- DP3.2: both shape and geometry of the expanded retractor (meaning that the further design is linked to the embodiment design phase).
- DP3.3 locking mechanism (this is a necessary requirement for any folding mechanism).

DPs for FR3.3:

- DP3.3.1: fix or fasten each plate on the origami sheet (Fig.5.5).
- DP3.3.2: make use of the hook-and-loop mechanism to connect the first and last plates (Fig. 5.5).

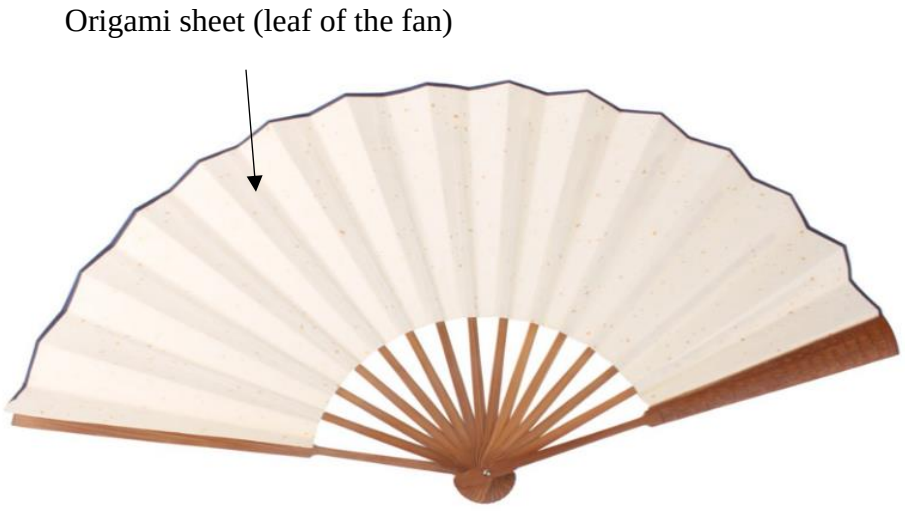


Figure 5.4 Origami sheet

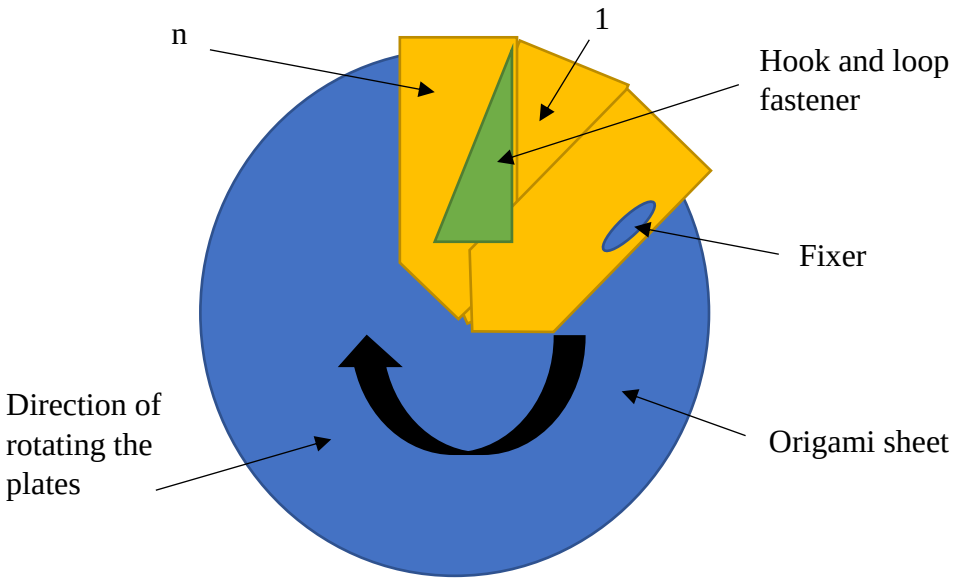


Figure 5.5 Locking mechanism illustration. 1: the first plate; n: the last plate

The overall FR structure is shown in Fig. 5.6. With this, one can further check the ADT-Axiom I in the following. For FR3.1, FR3.2 and FR3.3, the design meets the ADT-Axiom I (Fig. 5.7a). For

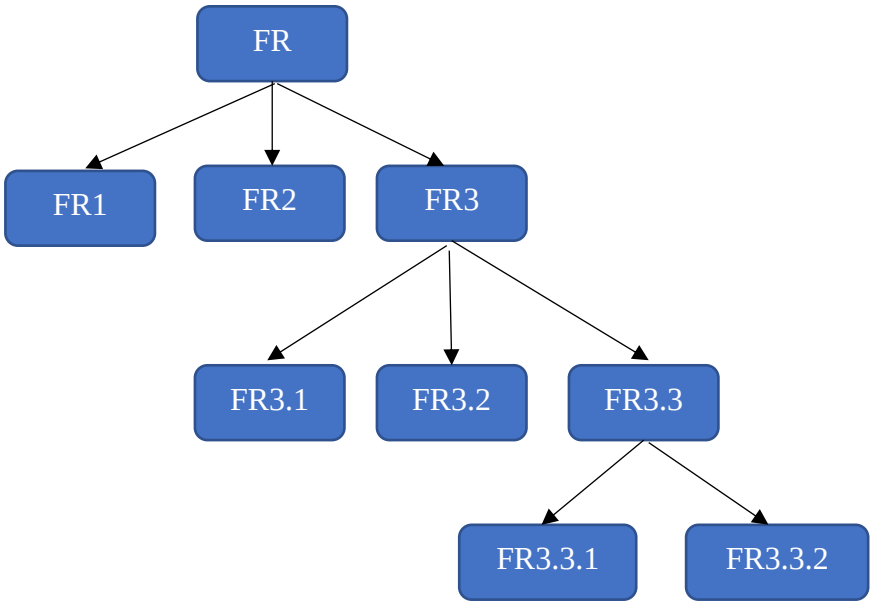


Figure 5.6 FR structure

FR3.3.1 and FR3.3.2, the design meets ADT-Axiom I (Fig. 5.7b). For the complete function decomposition (Fig. 5.6), the design meets ADT-Axiom I (Fig. 5.7c).

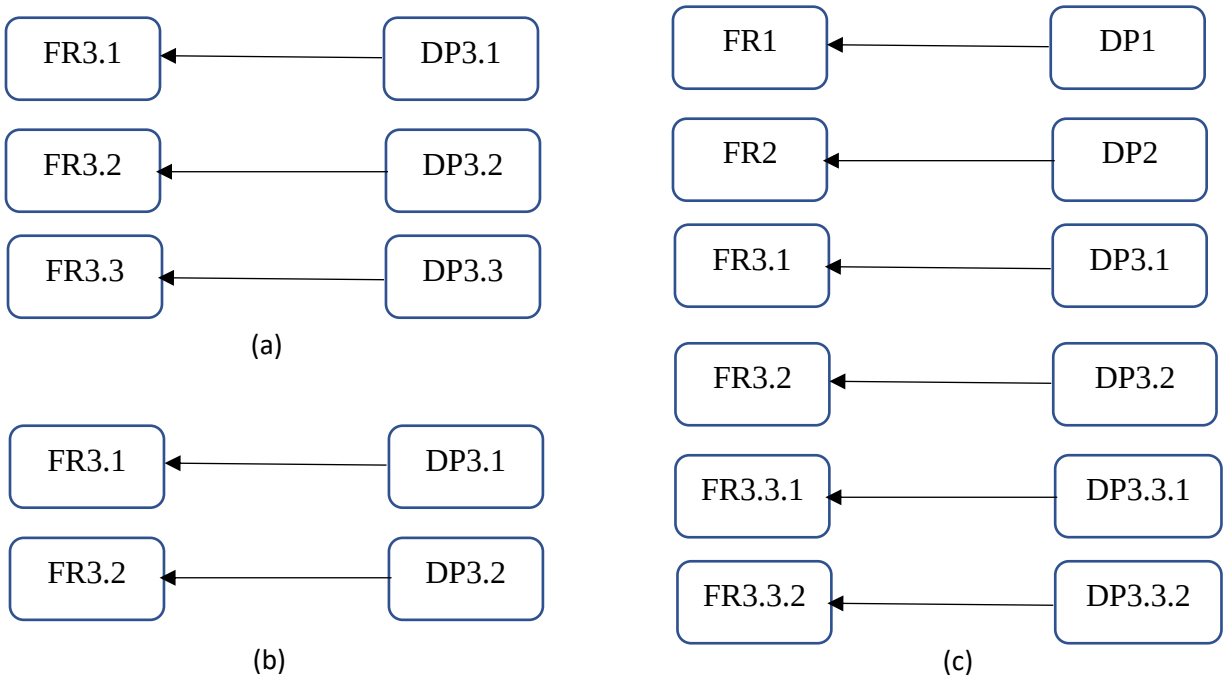


Figure 5.7 FR-DP correspondence

5.2.2 Embodiment design

To DP1, there are seven plates in total, each of which has the dimensions as shown in Fig. 5.8. The CR1 (FR1) is satisfied (i.e., 11.5 cm < 15 cm). The total thickness of retractor, including the thickness of the seven plates (7mm), the thickness of origami sheet (in total 3.6 mm, each of six gaps has two layers, each layer is 0.3mm) and the thickness of hook-and-loop fastener (1mm), meets the CR2 of FR3 (i.e., 11.6 mm < 15 mm).

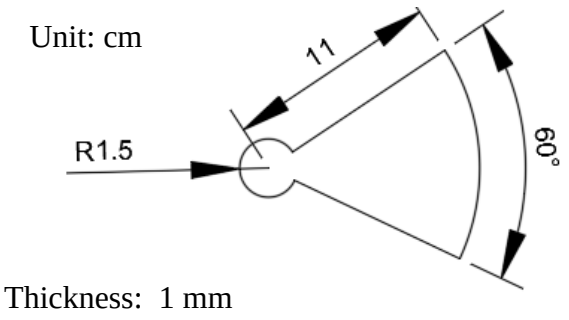


Figure 5.8 Shape and sizing of the plate

To DP2, the material PTFE was selected, which meets the constraint CR3 of the retractor (biocompatibility) and meets the performance requirement of FR2 (tensile strength of the PTFE is 31MPa (PTFE Handbook, 1996), which is greater than 18 MPa). To DP3.1, the geometry of the origami sheet is shown in Fig. 5.9, which meets the constraint CR2 (FR3). To DP3.2, there were seven plates and deployment of all the seven plates is shown in Fig 5.10. The expanded retractor meets constraint CR2 (FR3). To DP 3.3.1, Fig. 5.11 5.10 shows how the plates are fixed with the origami sheet. The hook-and-loop fastener material and geometry are shown in Figure 5.12. DP3.3.2: Figure 5.13 shows the complete retractor with (a) showing the collapsed/folded state and (b) showing the expanded or unfolded state.

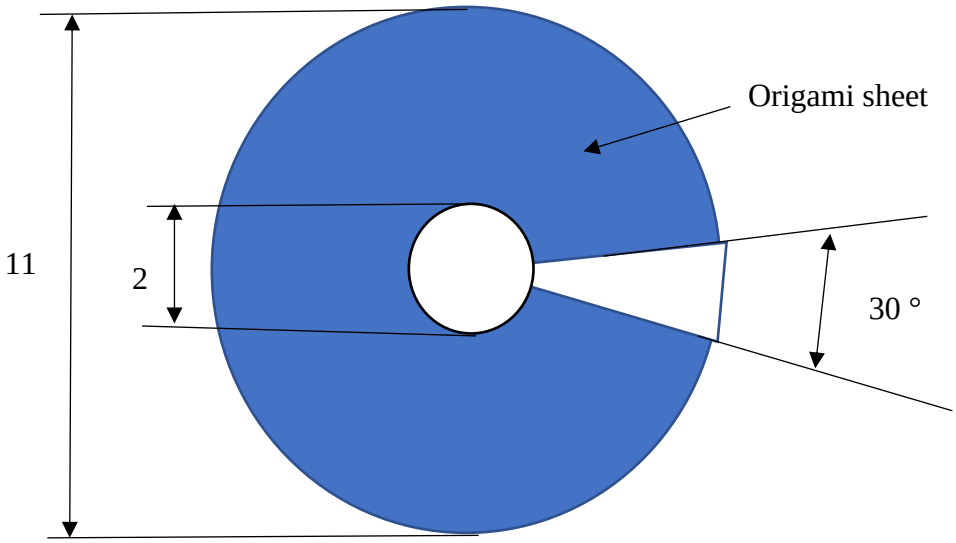


Figure 5.9 Origami sheet

Figure 5.10 Retractor prototype

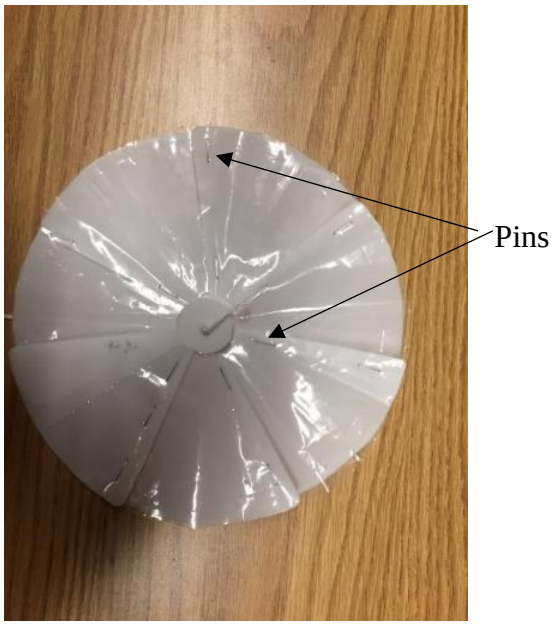


Figure 5.11 Plates fixed with origami sheet

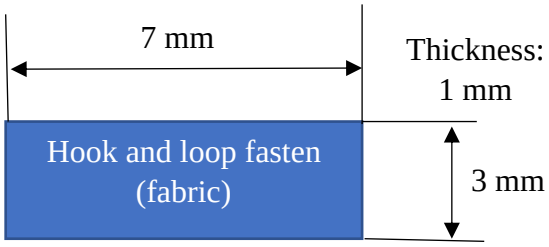
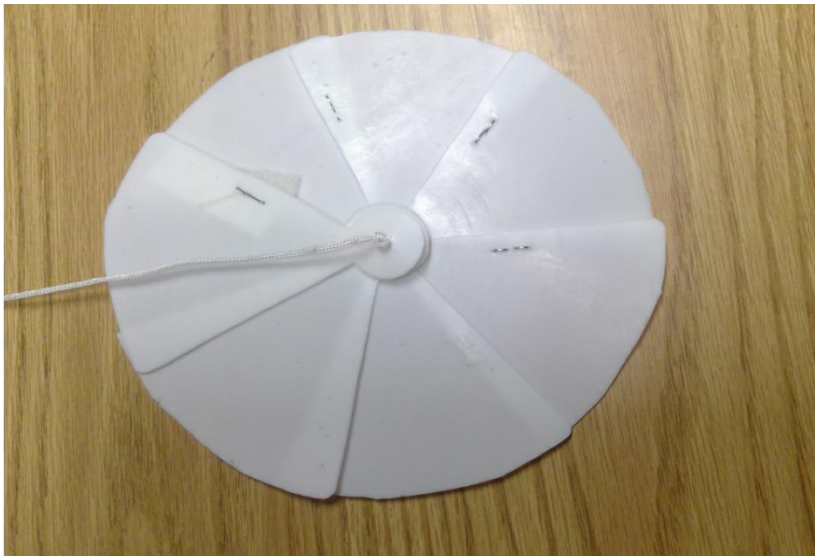


Figure 5.12 Hook-and –loop fastener

(a)



(b)

Figure 5.13 Collapsed and expanded retractor

5.3 Analysis

Two analyses were performed in the design of the retractor. The first analysis was performed on understanding whether the passer may penetrate the retractor, and this analysis helped to determine

both the material of the retractor and thickness of the retractor. The second analysis was performed on understanding whether the expansion of the retractor would hurt the tissue. The two analyses were finite element modeling with the help of ANSYS.

5.3.1 Simulation of the force resistance

For making sure that the material is enough to resist the force exerted by the suture passer (Fig. 5.14), simulation based on finite element modeling (FEM) was performed. Details of FEM are put in Appendix D. A PTFE board of 1 mm thickness was punched by the suture passer, and this means that a force of 54.0176 N (2 is the safety factor) is exerted on the board along the axial direction. The detailed information of the PTFE board is shown in Table 5.1. Fig. 5.15 shows the stress in the board. The maximum stress in the board is 5.6861×10^5 Pa, which is lower than the tensile strength (31 MPa) (PTFE Handbook, 1996). Therefore, the material is safe enough to resist the suture passer.

Table 5.1 Material properties in force resistance simulation

Resistant Material	**PTFE**
Density	220 Kg/ m^3
Young's Modulus	0.5 GPa
Dimension	30cm x 30cm x 1cm (L x W x H)
Suture passer material (Cook Medical, n.d.)	**Aluminum**
Density	270 Kg/ m^3
Gage	12
Length	16 cm

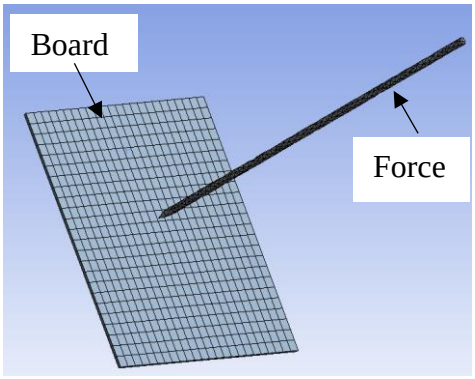


Figure 5.14 Force resistance

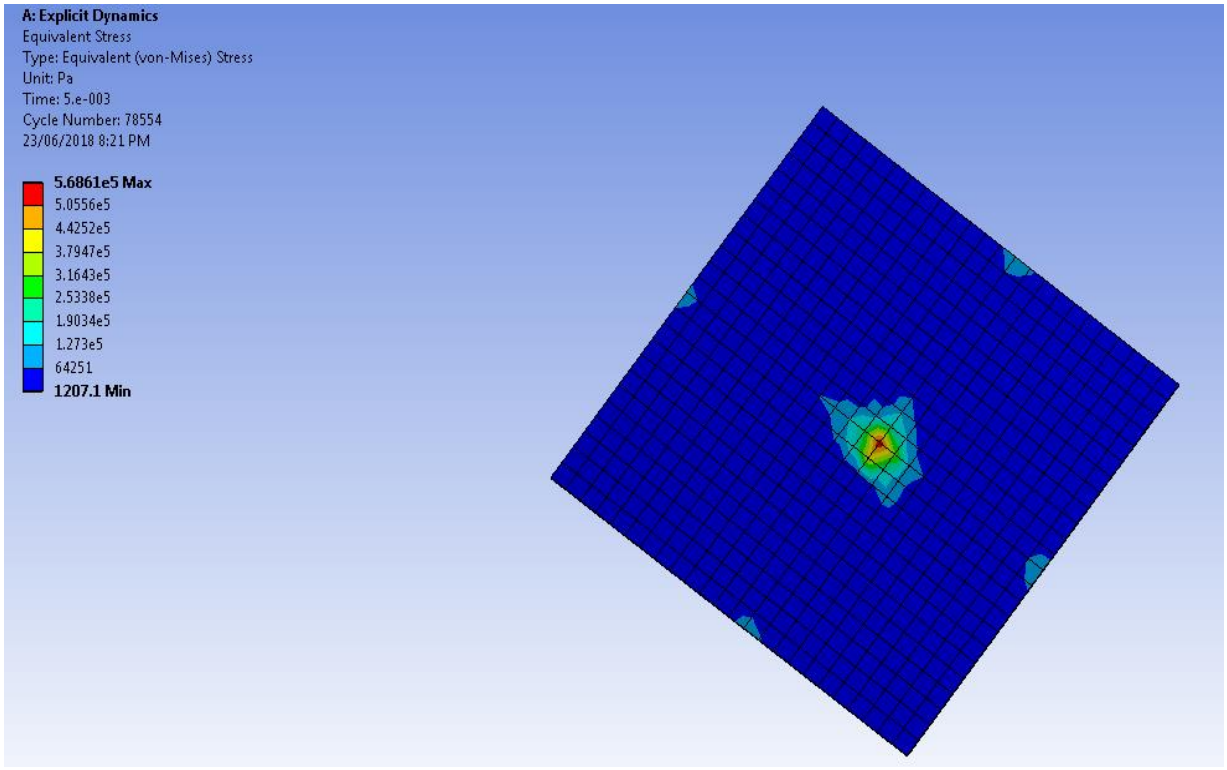


Figure 5.15 PTFE stress

5.3.2 Simulation of the expanding process of the retractor

The purpose of this simulation (Fig. 5.16) is to examine whether the intestine would be damaged while the retractor is being expanded on the top of the intestine tissue. The Poisson's ratio of the intestine tissue is 0.499 (Zheng, Mak, & Lue, 1999; Hing, Brooks, & Desai, 2007), and Young's Modulus is 944 KPa (Egorov, Schastlivtsev, Prut, Baranov, & Turusov, 2002). In the finite element modeling, the worst scenario of the loading on the intestine tissue was considered, which is when the retractor in the collapsed state. Therefore, the scenario considered in the FEM and simulation is that the collapsed retractor, the weight of which is 1.274 N (the sum of the weights of the seven plates), turns on the intestine tissue (see Fig. 5.16). Details of the finite element modeling can be seen in Appendix E.

Table 5.3 shows the results of the FEM simulation. From Table 5.3, it can be observed that the maximum stress is around 1300 Pa with the turning velocity ranging from 0.1 rad/s to 2 rad/s. The tensile strength of the intestine tissue is 1.289MPa (Egorov, Schastlivtsev, Prut, Baranov, & Turusov, 2002). As such, the retractor is soft, meeting the constraint of CR4 (see the previous discussion in Chapter 4) according to the definition of Chen et al. (2017).

Table 5.2 Material properties in retractor deploying simulation

Moving material	**PTFE**
Density	220 Kg/ m^3
Young's Modulus	0.5 GPa
Dimension	Described as Fig. 5.2
Testing material	**Intestine**
Young's Modulus	944KPa
Poisson's ratio	0.499
Dimension	60 cm x 40 cm x 20 cm (L x W x H)

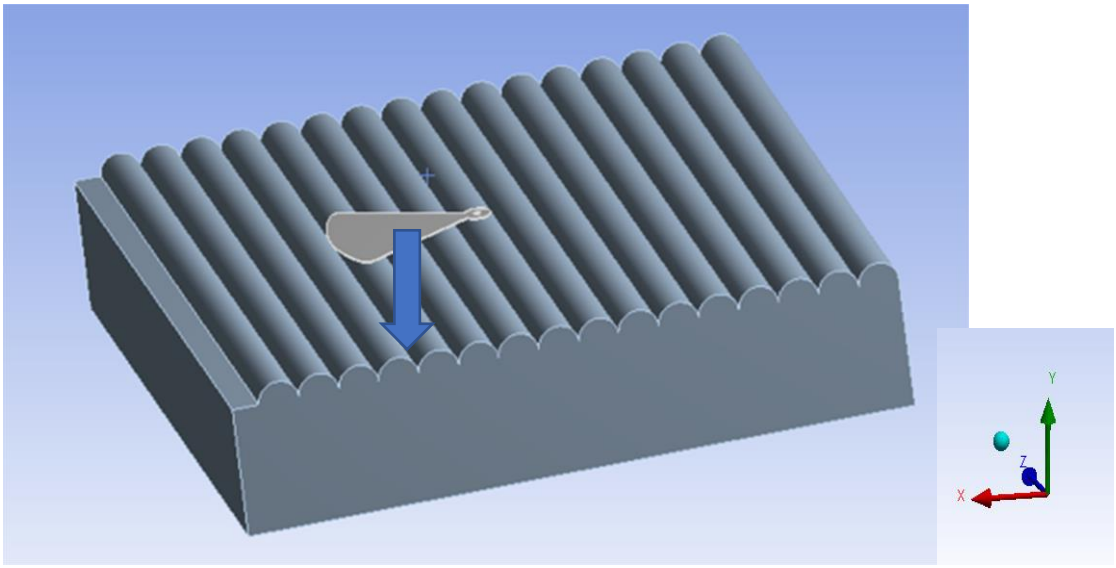


Figure 5.16 Simulation of expanding the retractor

Table 5.3 Results from different velocities

Velocity (rad/s)	X Direction Deformation (m)	-Y Direction Deformation (m)	Z Direction Deformation (m)	Stress (pa)	elastic strain (m/m)
0.1	5.15E-06	3.69E-05	2.78E-06	1301.5	1.46E-03
0.5	5.15E-06	3.67E-05	2.78E-06	1291.1	1.44E-03
1	5.15E-06	3.65E-05	2.79E-06	1261.2	1.41E-03
1.5	5.14E-06	3.69E-05	2.78E-06	1303.2	1.46E-03
2	5.14E-06	3.68E-05	2.79E-06	1299.5	1.45E-03

5.4 Conclusion

The complete design of the new retractor was presented in this chapter, which followed a more systematic general design process described in Fig. 3.3 of Chapter 3. It can be concluded that the retractor design is highly successful with all the requirements in the technical specification were satisfied. In comparison with Luo's retractor, the new retractor is biocompatible and soft. This chapter may also serve as a showcase of how design can be conducted more systematically, giving an implication that a "design machine" is possibly built in future.

CHAPTER 6

FABRICATION AND EXPERIMENT

6.1 Fabrication

For the fabrication process, the first step was to make seven plates by using manual cutting as shown in layout 2 of Figure 5.1. The plates were made round edge by using flat file to make them tissue friendly. The second step was to make a hole in the center of circle shape (see Fig. 5.1) with 1.5-millimeter diameter on the plate. The third step was to stack all seven plates by using a rope through the holes (Fig. 5.4). The plates must be tightly assembled so that there is no any relative movement among the plates in the vertical direction. The fourth step was to add the cover layer of LDPE (with 0.3 mm thickness) to all the plates using a staple. The final step was to put the hook and loop fastener on the first piece and last piece, respectively. Fig. 6.1a shows the collapsed retractor and Fig. 6.1b shows the expanded retractor. Further, it is the manual operation of the physician to switch the collapsed retractor to the expanded retractor (Fig. 6.2).

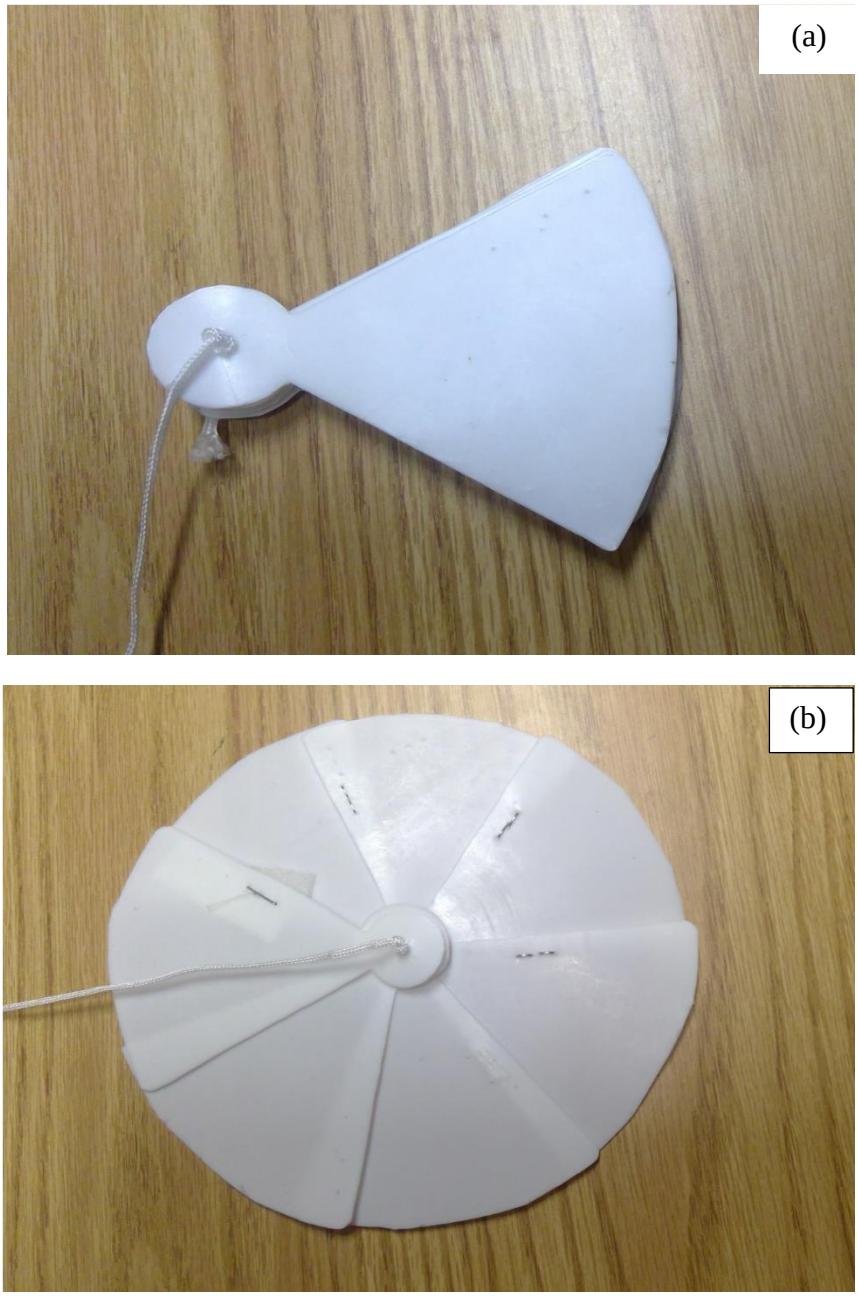


Figure 6.1 Collapsed and expanded retractor

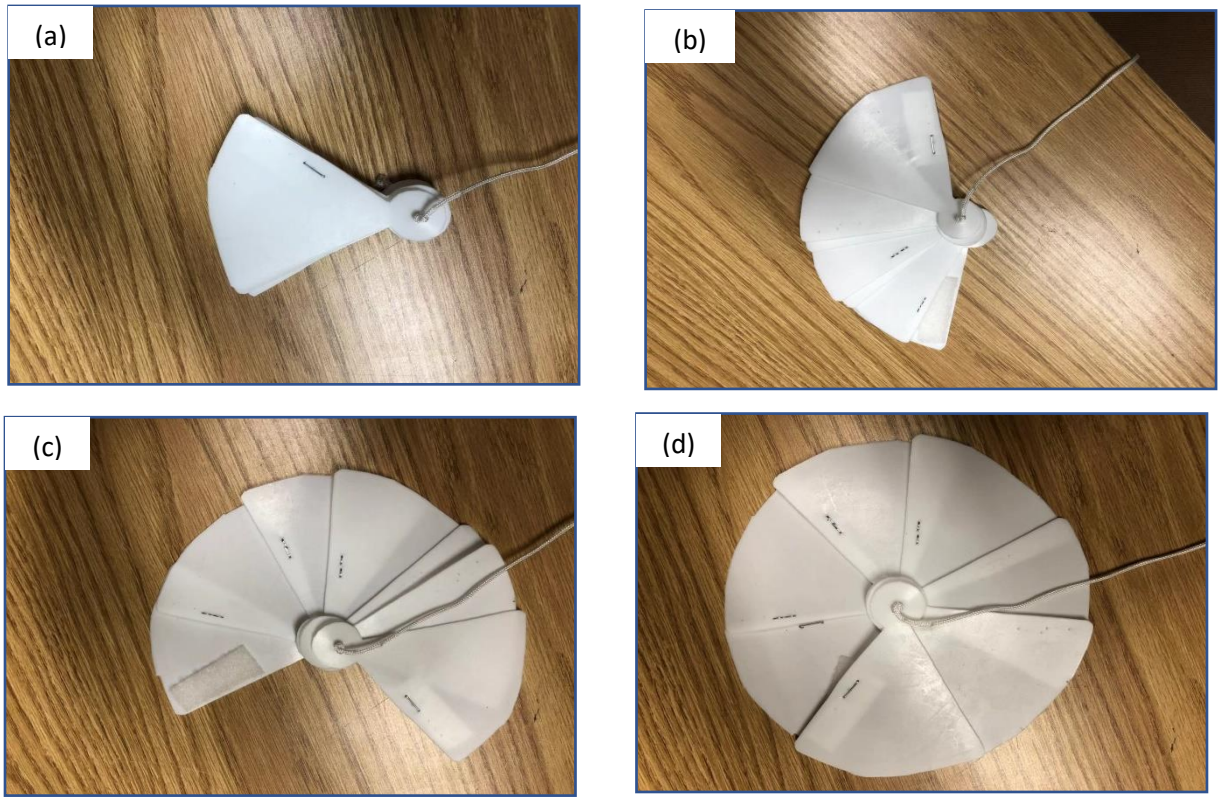


Figure 6.2 Manual operation to expand the retractor

6.2 Experiment

To demonstrate the effectiveness of the prototype of the retractor, experiment was performed on the porcine abdominal cavity. In this experiment, a size of about 10 cm x 10 cm hernia (Fig. 6.3) was made, then a surgical operation was conducted to fix the defective hernia with the prototype of the new design of the retractor. The experiment was quite successful. The entire surgery operation took about 40 minutes, which reduced the time of the operation by 37.5 % in comparison with the surgical operation with the spatula. The video of the entire operation was made available on YouTube https://www.youtube.com/watch?v=lyOXAtM6jhs&t=45s. Details of the experiment were given as follows:

Step 1: Made an incision (Fig. 6.4). Step 2: Inserted and expanded the retractor (Fig. 6.5). Step 3: Stitched the mesh (Fig 6.6). Step 4: Put the mesh into the abdominal cavity (Fig. 6.7). Step 5: Collapsed and took out the retractor (Fig. 6.8). Step 6: Closed the abdominal (Fig. 6.9).

Figure 6.3 10 cm x 10 cm hernia

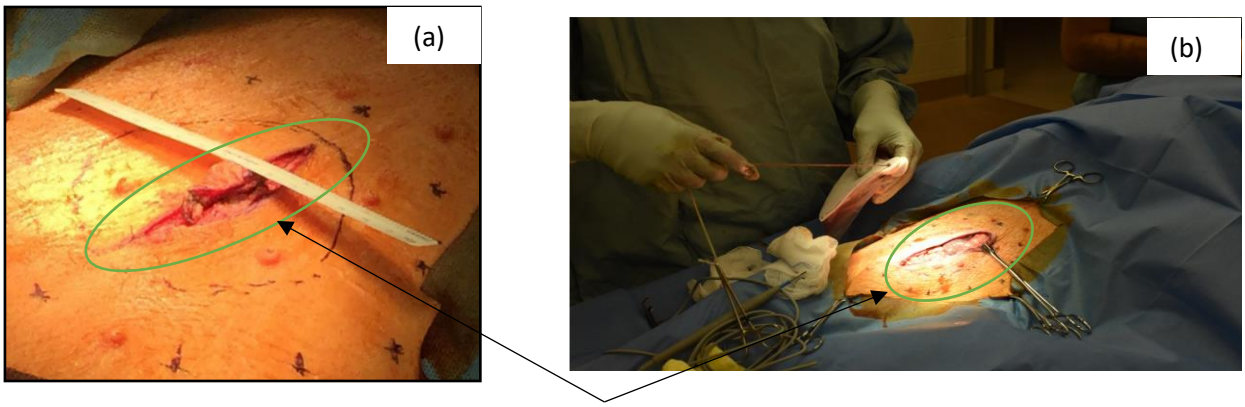


Figure 6.4 Incision making

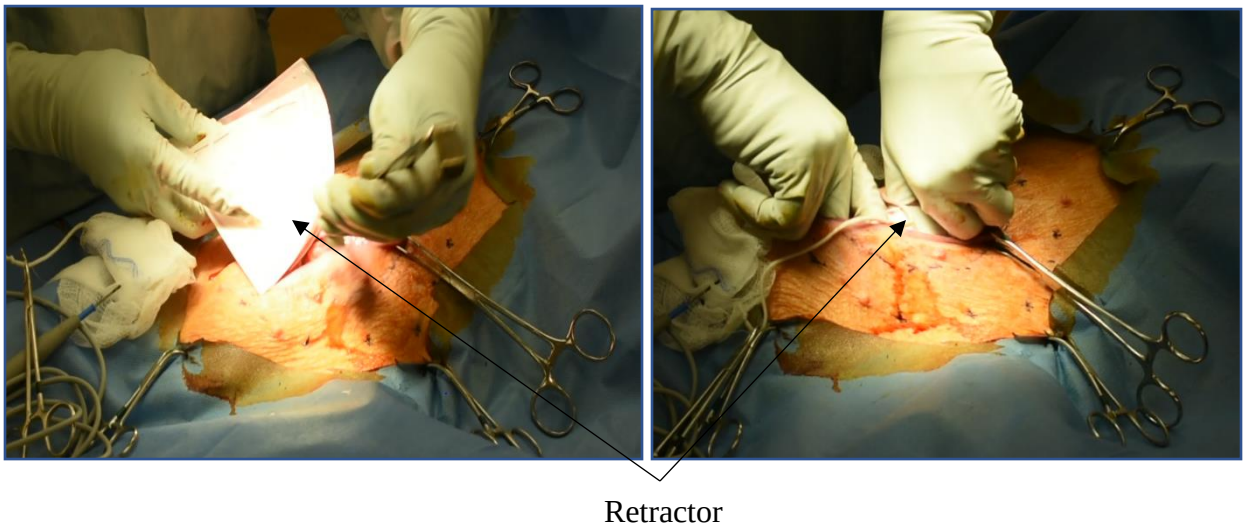


Figure 6.5 Inserting the retractor into the abdominal cavity

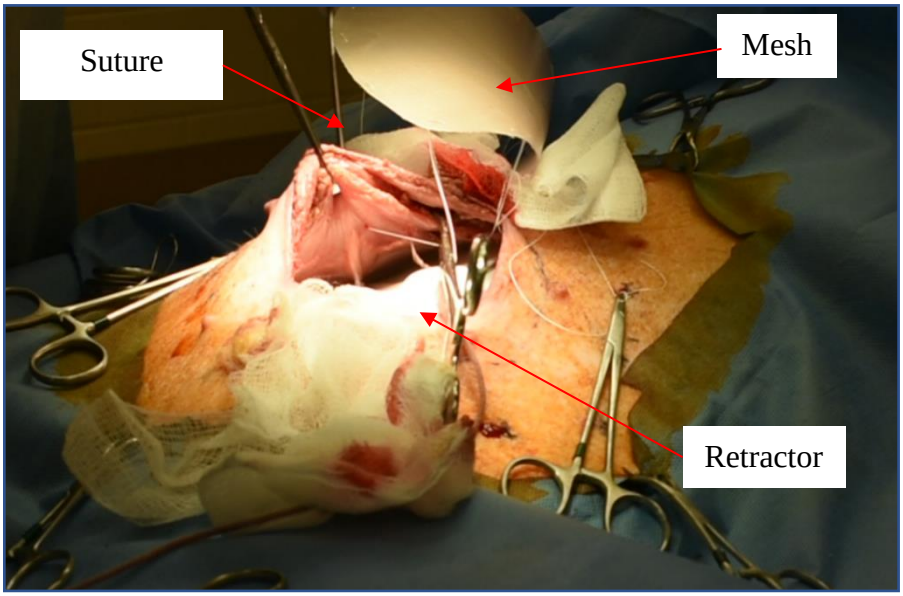


Figure 6.6 Stitching the mesh

Figure 6.7 Putting the mesh into the abdominal cavity

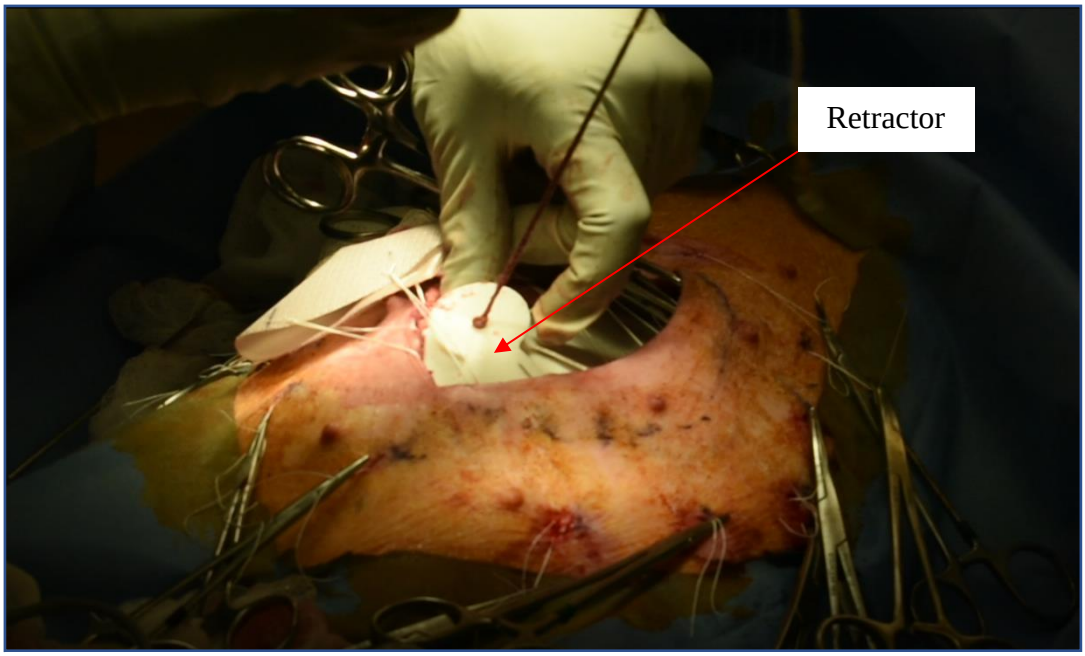


Figure 6.8 Folding and taking out the retractor of the cavity

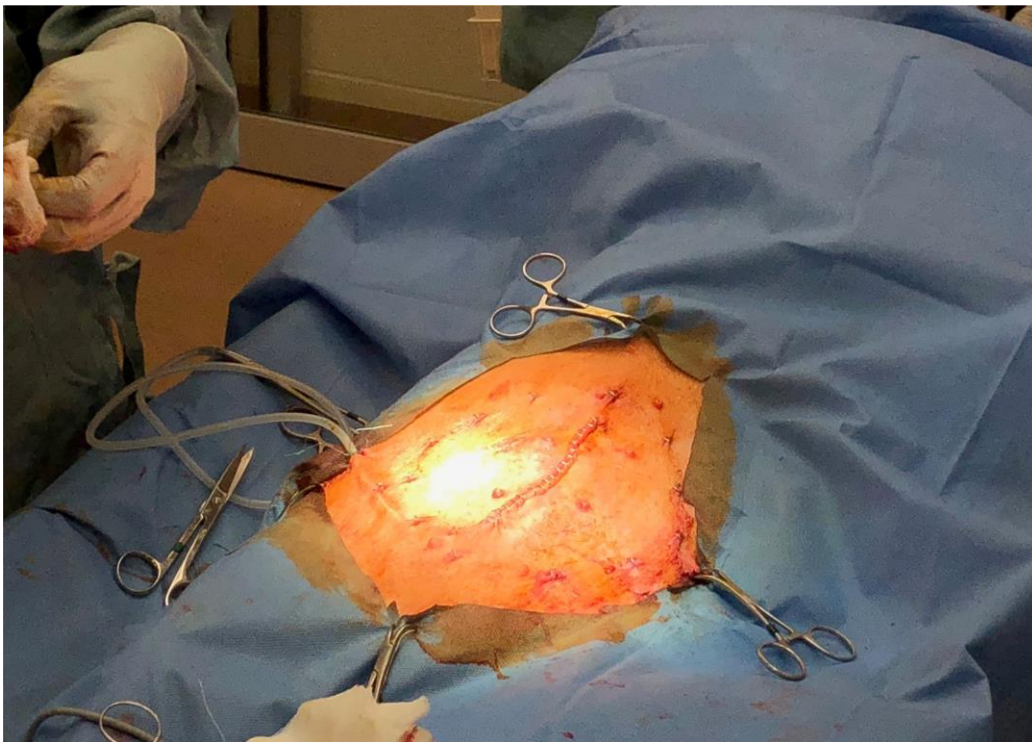


Figure 6.9 Closing the incision

6.3 Conclusion

In this chapter, the fabrication and assembly of the retractor were described. The experiment was presented. The experimental result shows that the new design of the retractor meets the requirement and can dramatically reduce the operation time of the hernia repair surgical operation. A summary of the improvements of the new retractor over Luo's retractor is presented in Table 6.1.

Table 6.1 Improvements of the new retractor over Luo's retractor

Design requirement	Luo's retractor	New retractor	Remark
The height of the retractor is less than 1.5cm.	2.4 cm.	1.16 cm.	The new retractor fulfilled the requirement.
Disposition gap of the retractor is less than 2.5cm.	The gap could be larger than 2.5cm occasionally.	Theoretically, there is no gap at all.	The new retractor fulfilled the gap requirement.
Biocompatibility requirement.	The material of Vinyl is toxic.	The material of PTFE is biocompatible.	The new retractor fulfilled the gap requirement.

CHAPTER 7

CONCLUSION

7.1 Overview and conclusions

The hernia repair surgical procedure is a highly demanded operation. Improving its effectiveness and efficiency has thus a significant impact on both the quality and cost of healthcare. The current practice of the hernia repair surgical procedure employs a device called spatula, which is difficult to operate as well as time consuming because it needs re-placement between the intestine and the inner wall of the abdomen for each stitching. Dr. Luo (a surgeon in Saskatchewan) pioneered the idea of the retractor in the hernia repair surgical procedure, which requires to place the retractor between the intestine and the inner wall of the abdomen once for all stitching. This thesis conducted a comprehensive study on Luo's retractor, particularly on its design. An intention of the study was also put on examining the existing general design theory and methodology on its integrity and effectiveness and applying it to retractor design. The objectives of the study are re-visited in the following:

Objective 1: To clarify several unresolved issues in the general design theory and methodology, especially developing a more formal model (or notation) that can more precisely describe a design process, including technical specification.

Objective 2: To develop a complete requirement model or technical specification for the retractor, including the requirement on the softness of the retractor such that the retractor design can be evaluated quantitatively and objectively.

Objective 3: To design, fabricate and test or experiment the new retractor to explore its improved behavior along with its performance over Luo's retractor against the technical specification.

The result of the study has demonstrated the achievement of the above objectives. Specifically, in Chapter 2, the existing general design theory and methodology was concisely summarized with a list of shortcomings identified. The two relevant device concepts, namely (i) folding-and-unfolding device and (ii) soft device, were also elaborated. Because the retractor is a kind of protective devices in medical technology, the protective devices in the context of medicine were also reviewed in this chapter. In Chapter 3, the shortcomings of the existing general design theory and methodology were carefully addressed, leading to several guidelines to help the application of the general design theory and methodology to design practices. A more formal design process model and a more formal design requirement model were proposed. In Chapter 4, by using the model of design requirement, the design requirement or technical specification for the retractor was developed. In Chapter 5, design of the retractor, including necessary analysis, was presented. In Chapter 6, fabrication of the new retractor and its clinical experiment were described.

The following conclusions can be drawn from this study:

(1) The concept of the retractor for the hernia repair surgical procedure is highly valid in terms of improving the quality of the procedure; specifically the successful rate of the procedure increases to 0.99 from $(0.99)^{NS}$, where NS is the number of stitches (typically, NS is 24).

(2) The procedure can reduce time from NS× STa×TS to NS×TS +STb, where STa is the set-up time for placing spatula (typically, STa is 30s), STb is the set-up time for placing retractor (typically, STb is 2 mins), and TS is the time for performing one stitch (typically, TS is 40s),

(3) The proposed design of the retractor can be built with an affordable cost (about $20 per retractor).

(4) The proposed model and guideline for the general design theory and methodology is conducive to improving its integrity and applicability.

(5) The new retractor significantly improves Luo's retractor, see Table 6.1 for details.

7.2 Contributions

The main contributions of the thesis are in the field of general design theory and methodology and in the field of the hernia repair surgical procedure, and they are discussed in detail below:

In the field of the general design theory and methodology, this thesis provides clarification of many confusions in the literature (see Chapter 2) and provides rules and guidelines to facilitate the actual execution of the general design process. The specific contributions are summarized below with indicating them to either theory or methodology.

(1) The definition of performances and constraints in both ADT and SDP, which are only vaguely described in the existing literature (theory).

(2) The two rules to distinguish the function requirement and constraint requirement in both ADT and SDP (theory).

(3) The guidelines for identifying the main function and auxiliary function and for defining the general function from the specific function in SDP (methodology).

(4) The guidelines for function decomposition in SDP (methodology).

(5) The guidelines for evaluation of Axiom I in ADT (methodology).

(6) The formal model for representing function, constraint and performance (theory).

(7) The formal general design process model (methodology).

In the field of hernia repair surgical procedure, this thesis has provided a well proven prototype of the retractor, which is novel and can lead to a significant improvement of the quality of the procedure and reduction of the operation time.

7.3 Future work

Commercialization of the new retractor is ready to go. This includes to refine the approach to the fabrication of the retractor for mass or batch production. It is noted that the current fabrication and assembly methods are ad-hoc, suitable for prototype development only. In this connection, the detailed design may be necessarily revised for a chosen fabrication method. As well, the biocompatibility of the material of the origami sheet and the fixer needs to be examined.

Another future work is how to automate the expanding process. Currently, this is done by physicians manually. It may be possible to improve the design so that the process can be automated.

Finally, a robotic hernia repair surgical procedure is worthy of study, as this may further improve the efficiency of the procedure and reduce the work load of physicians.

REFERENCES

(n.d.). Retrieved from Laparocopic Ventral Hernia Repair Patient Information From Sages: https://www.sages.org/publications/patient-information/patient-information-for-laparoscopic-ventral-hernia-repair-from-sages/

(n.d.). Retrieved from Ventral Hernia - Symptoms & Treatment: http://www.mountsinai.org/patient-care/service-areas/surgery/divisions/general-surgery/hernia-surgery/ventral-hernia.

(n.d.). Retrieved from Axiomatic design: https://en.wikipedia.org/wiki/Axiomatic_design

(2018, Feburary). Retrieved from U.S Food & Drug Administration: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/HerniaSurgicalMesh/default.htm

Cai, M., Lin, Y., Han, B., Liu, C., & Zhang, W. (2017, September). On a Sinple and Efiicient Approach to Probability Distrbution Function Aggregation. *IEEE Transactions on Systems, Man, and Cybernetics: Systems, 47*(9), 2444-2453. doi:10.1109/TSMC.2016.2531647

Cao, L., Dolovich, A. T., & Zhang, W. (2015). Hybrid Compliant Mechanism Design Using a Mixed Mesh of Flexure Hinge Elements and Beam Elements Through Topology Optimization. *Journal of Mechanical Design, 137*(9), 092303-092303-10. doi:10.1115/1.4030990

Cao, L., Dolovich, A. T., Chen, A., & Zhang, W. (2018, March). Topology optimization of efficient and strong hybrid compliant mechanisms using a mixed mesh of beams and flexure hinges with strength control. *Mechanism and Machine Theory, 121*, 213-227.

Cao, L., Dolovich, A. T., Schwab, A. L., L., H. J., & Zhang, W. (2015). Toward a Unified Design Approach for Both Compliant Mechanisms and Rigid-Body Mechanisms: Module Optimization. *Journal of Mechanical Design, 137*(12), 122301-122301-10. doi:DOI: 10.1115/1.4031294

Chen, A., Yin, R., Cao, L., Yuan, C., Ding, H., & Zhang, W. (2017). Soft robotics: Definition and research issues. *24th International Conference on Mechatronics and Machine Vision in Practice (M2VIP).* doi:10.1109/m2vip.2017.8267170

Cook Medical. (n.d.). (Cook) Retrieved January 11, 2018, from https://www.cookmedical.com/data/IFU_PDF/T_PAS_REV1.PDF

Crovella, F., Bartone, G., & Fei, L. (2008). *Incisional hernia.* Milan: Springer.

Egorov, V. I., Schastlivtsev, I. V., Prut, E. V., Baranov, A. O., & Turusov, R. A. (2002). Mechanical properties of the human gastrointestinal tract. *Journal of Biomechanics, 35*(10), 1617-1625.

Fan, L., Cai, M., Lin, Y., & Zhang, W. (2015). Axiomatic design theory: further notes and its guideline to applications. *International Journal of Materials and Product Technology,, 51*(4), 359. doi:10.1504/ijmpt.2015.072557

Farberov, A. (2011). *U.S. Patent No. US8011504B1*.

Fu, L., Yin, R., X.J., W., Zhang, T., Chen, A., Zhang, E., & Zhang, W. (2015). The folding system: its concept and classification. Qingdao.

Guo, L., & Zhang, W. (2001). Kinematic analysis of a rice transplanting mechanism with eccentric planetary gear trains. *Mechanism and Machine Theory, 36*(11-12), 1175-1188. doi:10.1016/S0094-114X(01)00052-0

Hing, J. T., Brooks, A. D., & Desai, J. P. (2007). A biplanar fluoroscopic approach for the measurement, modeling, and simulation of needle and soft-tissue interaction. *Medical Image Analysis, 11*(1), 62-78. doi:10.1016/j.media.2006.09.005

Knippenberg, R. V., Habraken, A., & Teuffel, P. (2016). Deployable Structures Using Non-singular Rigid Foldable Patterns. *Procedia Engineering, 155*, 388-397. doi:10.1016/j.proeng.2016.08.042

Krause, L. (2018, July 7). Retrieved from Ventral Hernia: http://www.healthline.com/health/ventral-hernia#overview1.

Krumhauer, P. (1974). *Rechnerunterstützung für die Konzeptphase der Konstruktion.* Dissertation, TU Berlin.

Leonard, J. (1999, December 01). Systems Engineering Fundamentals. doi:10.21236/ada372635

Lin, Y., & Zhang, W. (2004). Towards a novel interface design framework: function–behavior–state paradigm. *International Journal of Human-Computer Studies, 61*(3), 259-297. doi:https://doi.org/10.1016/j.ijhcs.2003.11.008

Luo, Y., Raj, M., Zhang, W., Lim, J., Y, X., Wright, F., & Dai, Z. (2017). Massive Ventral Hernia Repair: A Novel Technique with an Innovative Device. *Surgery: Current Trends and Innovations, 1*(003). doi:10.24966/SCTI-7284/100003.

Muddada, S. S. (2014). *Application of design theory and methodoly to the design of a solid-state fermenter*. Master of Science Thesis, Department of Mechanical Engineering, University of Saskatchewan.

Neyret, P., André, O., & Rochetin, P. (2009). *U.S. Patent No. WO2009077695A3.*

Noritsugu, T., Sasaki, D., & Takaiwa, M. (2002). Proceedings of the JFPS International Symposium on Fluid Power. *Application of Pneumatic Soft Mechanism to a Human Friendly Robot, 2002*(5-1), 61-66. doi:10.5739/isfp.2002.61

Pahl, G., Beitz, W., & Feldhusen, J. (2007). *Engineering Design: a systematic approach.* London: Springer.

PTFE Handbook. (1996). Washington. Retrieved from http://www.rjchase.com/ptfe_handbook.pdf

Rateni, G., Cianchetti, M., Ciuti, G., Menciassi, A., & Laschi, C. (2015). Design and development of a soft robotic gripper for manipulation in minimally invasive surgery: A proof of concept. *Meccanica,* 2855-2863. doi:10.1007/s11012-015-0261-6.

Small intestine. (2018, November). Retrieved from Wikipedia: https://en.wikipedia.org/wiki/Small_intestine

Suh, N. P. (2010). *The principles of design.* New York: Oxford University Press.

Wang, E., & Liu, B. (2009). *China Patent No. CN 201216601 Y.*

Wang, W., Wang, H., Ding, J., Furuta, K., Kanno, T., Ip, W., & Zhang, W. (2016). On domain modelling of the service system with its application to enterprise information systems. *Enterprise Information Systems, 10*(1). doi:10.1080/17517575.2013.810784.

Zhang, T., Zhang, W., & Gupta, M. M. (2018, June). An underactuated self-reconfigurable robot and the reconfiguration evolution. *Mechanism and Machine Theory, 124*, 248-258.

Zhang, W. (1994). *An integrated environment for CAD/CAM of mechanical systems.* Delft university of technology. Delft: Delft University of Technology.

Zhang, W. (2018). *Systematic design process.* Lecture note 4, University of Saskatchewan, Saskatoon. Retrived from http:// www.engr.usask.ca\classes\me\886 on March 1, 2019,

Zhang, W. J., & Luttervelt, C. A. (2011). Toward a resilient manufacturing system. *CIRP Annals - Manufacturing Technology, 60*(1), 469-472. doi:0.1016/j.cirp.2011.03.041

Zhang, W., & Wang, J. (2016). Design theory and methodology for enterprise systems. *Enterprise Information Systems, 10*(3), 245-248. doi: 10.1080/17517575.2015.1080860

Zhang, W., Li, J., & Zettl, B. (2012). Classification of design theories and methodologies for effective industrial applications. *7th IEEE Conference on Industrial Electronics and Applications (ICIEA).* doi:10.1109/iciea.2012.6360915

Zhang, W., Lin, J., & Sinha, N. (2005). On the Function-Behavior-Structure Model for Design. *the 2nd cden conference*, (p. 8). Alberta.

Zheng, Y., Mak, A. F., & Lue, B. (1999, April). Objective assessment of limb tissue elasticity: Development of a manual indentation procedure. *Journal of rehabilitation research and development, 36*(2), 71-85.

APPENDIX A

PACKING CASE STUDY

The design of the packing machine for carpet tiles is completely drawn from the literature (Pahl, Beitz, & Feldhusen, 2007). According to Pahl, Beitz, & Feldhusen (2007), the packing machine has several main functions, including separating offcuts, checking quality, counting tiles, combining in lots and packing, as shown in the form of a block diagram in Figure A.1.

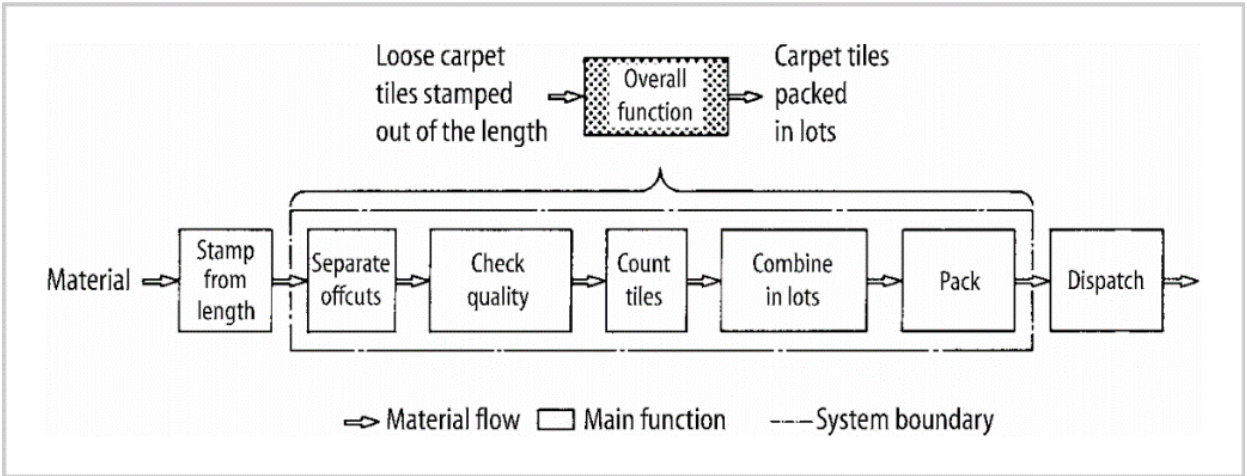


Figure A.1 Main flow for the packing of carpet tiles

At the same time, the authors introduced several auxiliary functions, which consists of removing offcuts, removing rejects, sending signal to combine n tiles into one lot and supplying packing material, as the function structure shown in Figure A.2. The four functions are defined as auxiliary, because it would not change the overall function with absence of them. They are supplementary functions, helping main functions to do those tasks better.

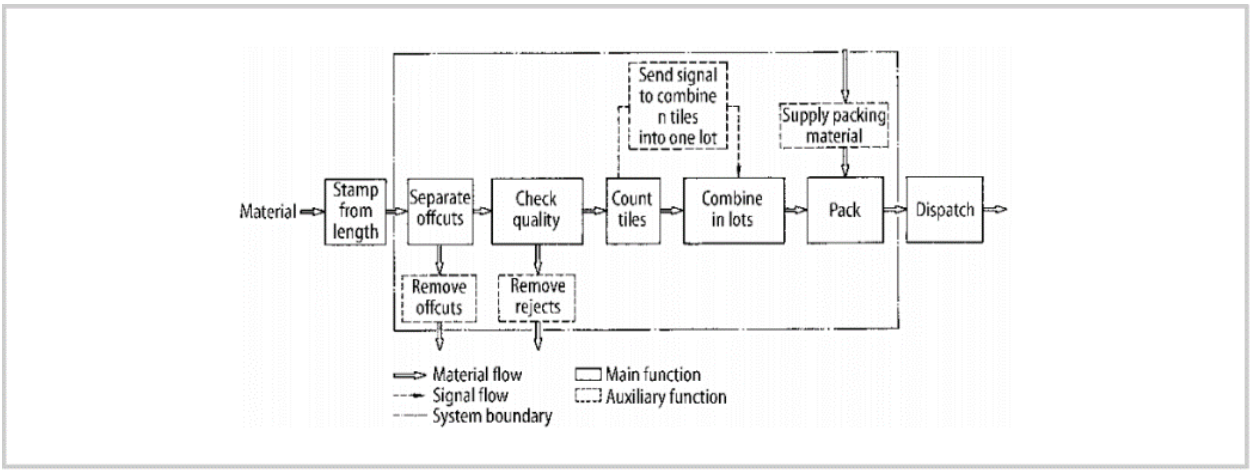


Figure A.2 Function structure for the packing of carpet tiles

APPENDIX B

FCBPSS

FCBPSS is an abbreviation of Function, Context, Behaviour, Principle, State, and Structure, and it is the general knowledge architecture of any system (Zhang & Wang, 2016; Zhang et al., 2005). Specifically, according to Zhang and Wang (2016), Function refers to the role a system plays; Context refers to the condition and environment under which a function is played by a system; Behaviour refers to the input (stimuli)– output (response) relationship; State refers to the property or characteristics of a system (subsystem, component); Structure refers to a set of components with their connections.

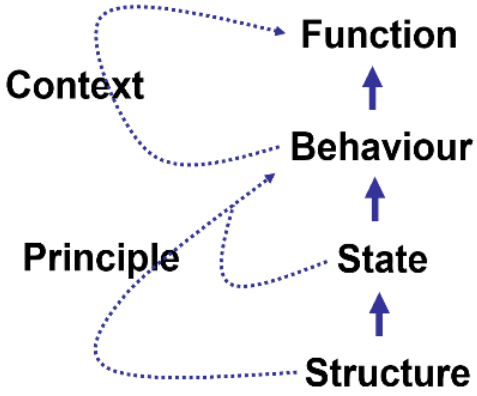


Figure B.1 FCBPSS

APPENDIX C

FORCE MEASUREMENT

For determining the force when the suture passer reaches the retractor, we set up such a testbed (Fig. C.1) to measure the range of forces. In this testbed, it consists of three wood blocks. Between the wood block 1 and 2, the electronic scale was underneath the pig piece. The pig piece, taken right after a pig was dead, was nailed into the wood blocks as shown Fig. C.1.

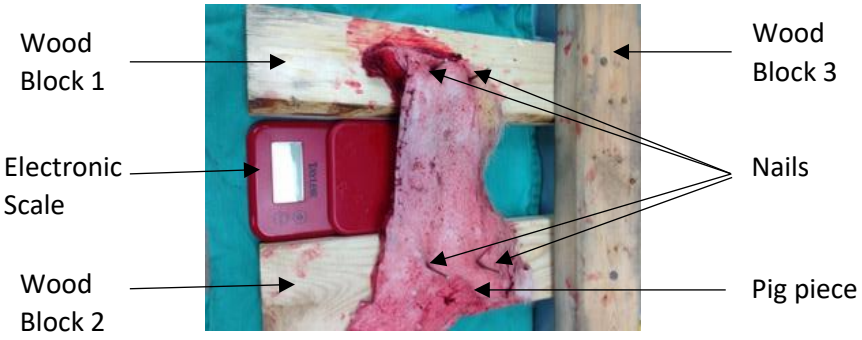


Figure C.1 Force Measurement Testbed

Before moving to the experiment, tare the electronic scale each time (Fig. C.2).

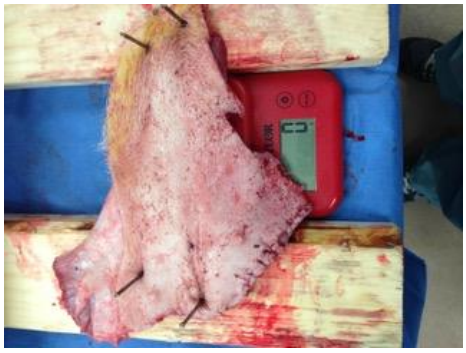


Figure C.2 Adjusting the electronic scale

Then a few points were marked by the blade as the same as it is done in a clinical surgery. Here we highlighted those points by using a mark (Fig. C.3).

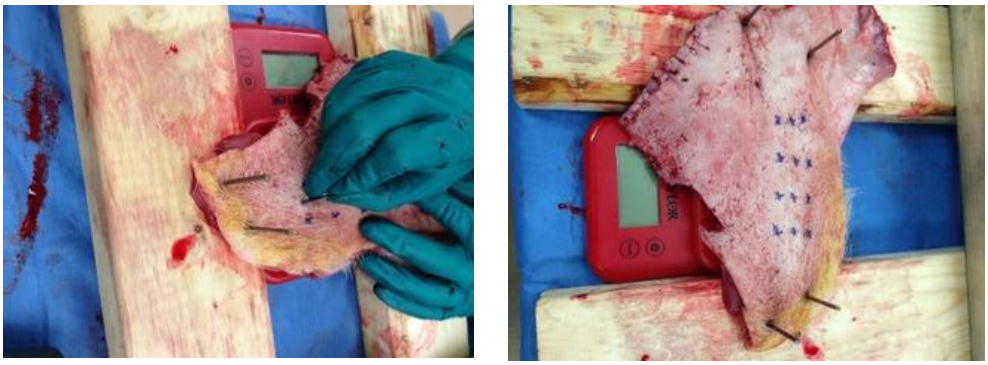


Figure C.3 Marking the point

The last step was to simulate the process of puncture by using suture passer (Fig. C.4). The maximum force was recorded from the electronic scale (Table C.1). Here (*i*,*j*) means the *i*th pig, the *j*th piece, P stands for pig.

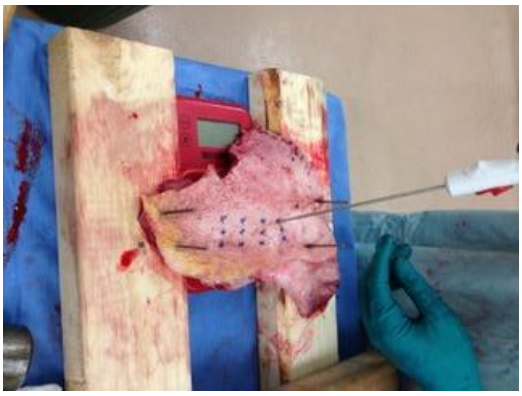


Figure C.4 The process of puncture

Table C.1 Recorded data

	P(1,1) (g)	P(1,2) (g)	P(2,1) (g)	P(2,2) (g)	P(3, 1) (g)	P(3, 2) (g)
1	1069	1277	1286	701	830	2756
2	935	1730	1321	1873	914	2231
3	1678	1422	1865	2158	878	2161
4	925	1436	1873	2089	617	1590
5	887	1639	1093	2569	800	1019
6	1629	880	1586	1037	2073	1840
7	1016	1122	2509	1749	1512	2127
8	953	1615	2649	1419	1671	813
9	1799	679	1283	1678	2178	1136
10	1425	1215	1560	2295	878	1158
11				1243		1385
12				1043		1942
13						2052
14						1712
15						1603
16						1558
17						998
18						1224
19						987
20						1713
21						1680
22						1006
23						1340
24						1051
25						1258

Then, we changed the unit “Gram” to “Newton” by using force of gravity on earth (**9.8N/kg)**. We got the following table.

Table C.2 Force data

	F1,1(N)	F1,2(N)	F2,1(N)	F2,1(N)	F3,1(N)	F3,2(N)
1	10.4762	12.5146	12.6028	6.8698	8.134	27.0088
2	9.163	16.954	12.9458	18.3554	8.9572	21.8638
3	16.4444	13.9356	18.277	21.1484	8.6044	21.1778
4	9.065	14.0728	18.3554	20.4722	6.0466	15.582
5	8.6926	16.0622	10.7114	25.1762	7.84	9.9862
6	15.9642	8.624	15.5428	10.1626	20.3154	18.032
7	9.9568	10.9956	24.5882	17.1402	14.8176	20.8446
8	9.3394	15.827	25.9602	13.9062	16.3758	7.9674
9	17.6302	6.6542	12.5734	16.4444	21.3444	11.1328
10	13.965	11.907	15.288	22.491	8.6044	11.3484
11				12.1814		13.573
12				10.2214		19.0316
13						20.1096
14						16.7776
15						15.7094
16						15.2684
17						9.7804
18						11.9952
19						9.6726
20						16.7874
21						16.464
22						9.8588
23						13.132
24						10.2998
25						12.3284

The dataset is available on https://github.com/zzzz88/Force-data-analysis/blob/master/Force%20data.xlsx.Here is the R Markdown file to compare the sample means of different pieces of the same pig and different pigs

Tidy the data and combine the data from the same pigs into the same columns

```
library(readxl)

forcedata <- read_excel("force data.xlsx")
```

```
## New names:
## * `` -> `..1`
## * `PIECE2(g)` -> `PIECE2(g)..3`
## * `PIECE 1(g)` -> `PIECE 1(g)..4`
## * `PIECE2(g)` -> `PIECE2(g)..5`
## * `PIECE 1(g)` -> `PIECE 1(g)..6`

colnames(forcedata) <- c( "force_measurement","pig1_piece1","pig1_piece2",
                          "pig2_piece1","pig2_piece2",
                          "pig3_piece1","pig3_piece2")
forcedata$force_measurement <- 1:nrow(forcedata)
df <- as.data.frame(sapply(forcedata, as.numeric))
library(reshape2)
cmbdata1 <-melt(df,id.vars = "force_measurement",
                measure.vars = c("pig1_piece1","pig1_piece2"),
                variable.name = "pig1", na.rm = TRUE)
cmbdata2 <-melt(df,id.vars = "force_measurement",
                measure.vars = c("pig2_piece1","pig2_piece2"),
                variable.name = "pig2", na.rm = TRUE)
cmbdata3 <-melt(df,id.vars = "force_measurement",
                measure.vars = c("pig3_piece1","pig3_piece2"),
                variable.name = "pig1", na.rm = TRUE)
```

Calculate the P values

```
P1 <-t.test(df$pig1_piece1,df$pig1_piece2,paired = FALSE,var.equal = FALSE,na.rm
        =TRUE)
P2 <-t.test(df$pig2_piece1,df$pig2_piece2,paired = FALSE,var.equal = FALSE,na.rm
        =TRUE)
P3 <-t.test(df$pig2_piece1,df$pig3_piece2,paired = FALSE,var.equal = FALSE,na.rm
        =TRUE)
P4 <-t.test(cmbdata1$value,cmbdata2$value,paired = FALSE,var.equal = FALSE)
P5 <-t.test(cmbdata1$value,cmbdata3$value,paired = FALSE,var.equal = FALSE)
P6 <-t.test(cmbdata3$value,cmbdata2$value,paired = FALSE,var.equal = FALSE)
P.value <- c(P1$p.value,P2$p.value,P3$p.value,P4$p.value,P5$p.value,P6$p.value)


P.value

## [1] 0.660290312 0.840406720 0.395741178 0.005429335 0.126715114 0.124301058
```

According the results, the P-values of P1, P2 and P3 are all great than 0.5, indicating there are no significant differences between different pieces of the same pigs. The P-values of P4 shows that there is difference between different pigs.

APPENDIX D

FINITE ELEMENT MODELING FOR SIMULATION OF FORCE RESISTANCE

The stepwise force resistance simulation procedure in Ansys Workbench is discussed below:

1. Define geometrical object as in Figure D.1, Figure D.2 and Figure D.3 with the parameters.
2. Define the type of material as show in Table 5.1.
3. Generate mesh as the Figure D.4 shows.
4. Apply the force load as shown in Figure D.5.
5. Apply the support as shown in Figure D.6.
6. Complete the model.

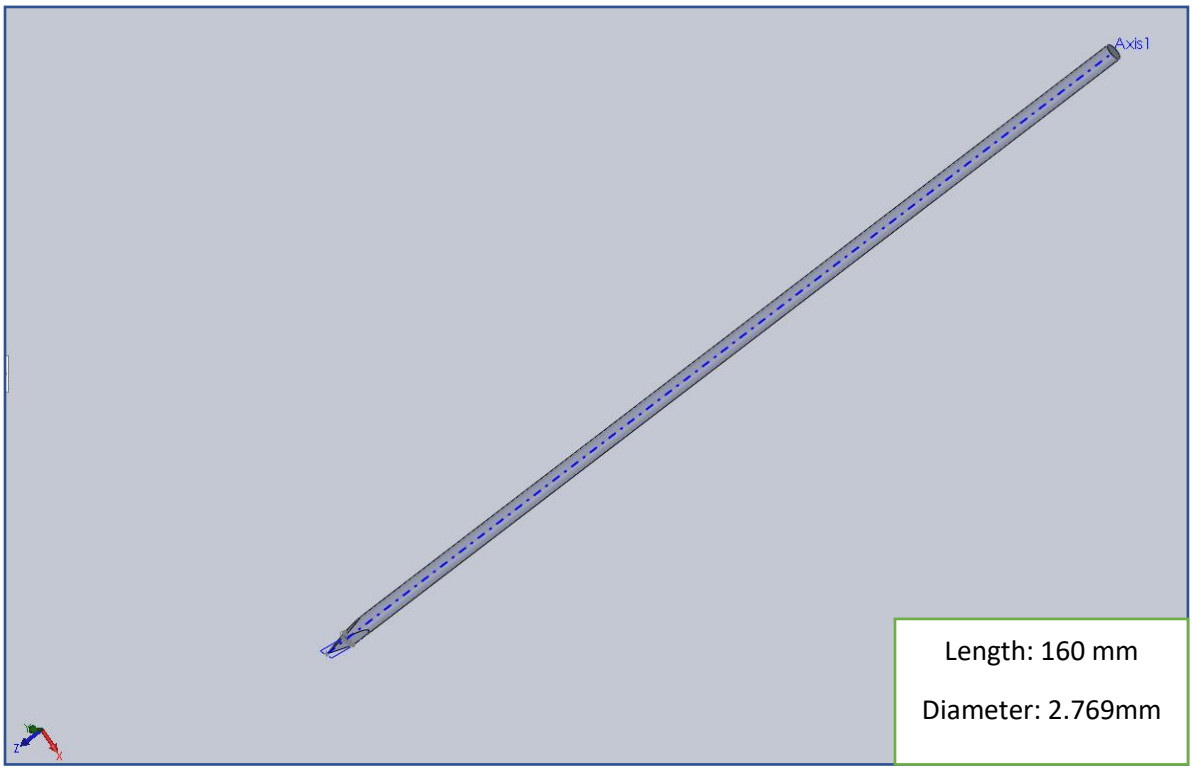


Figure D.1 Suture passer geometry

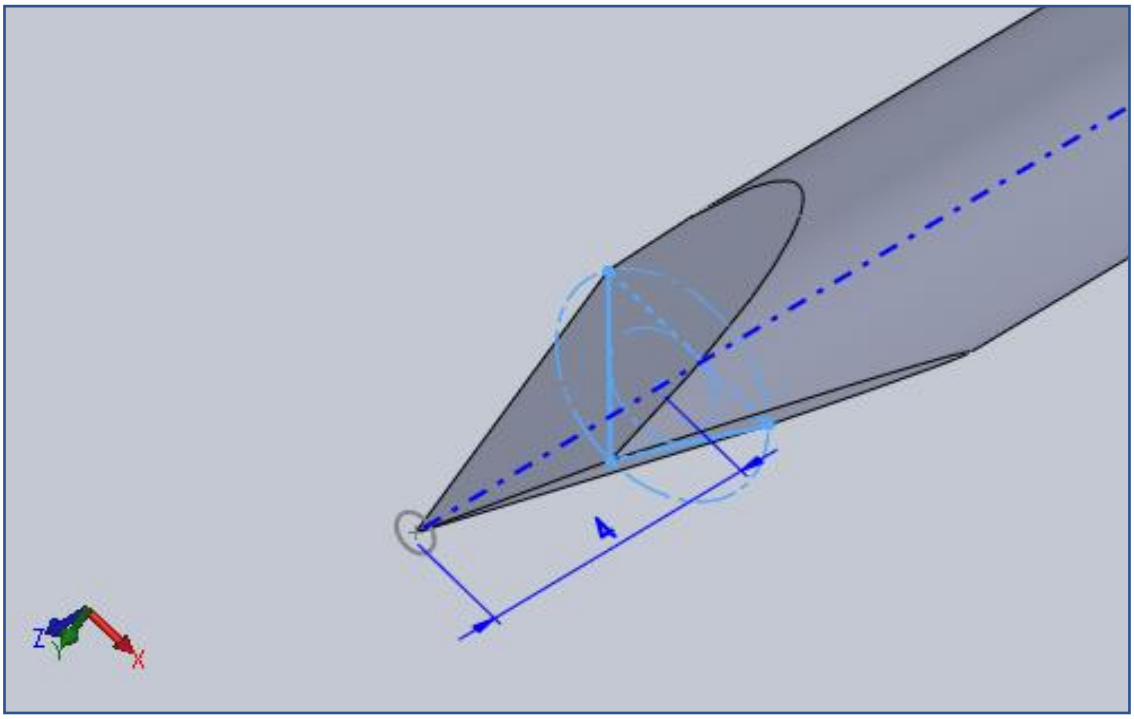


Figure D.2 Details of suture passer sharp end

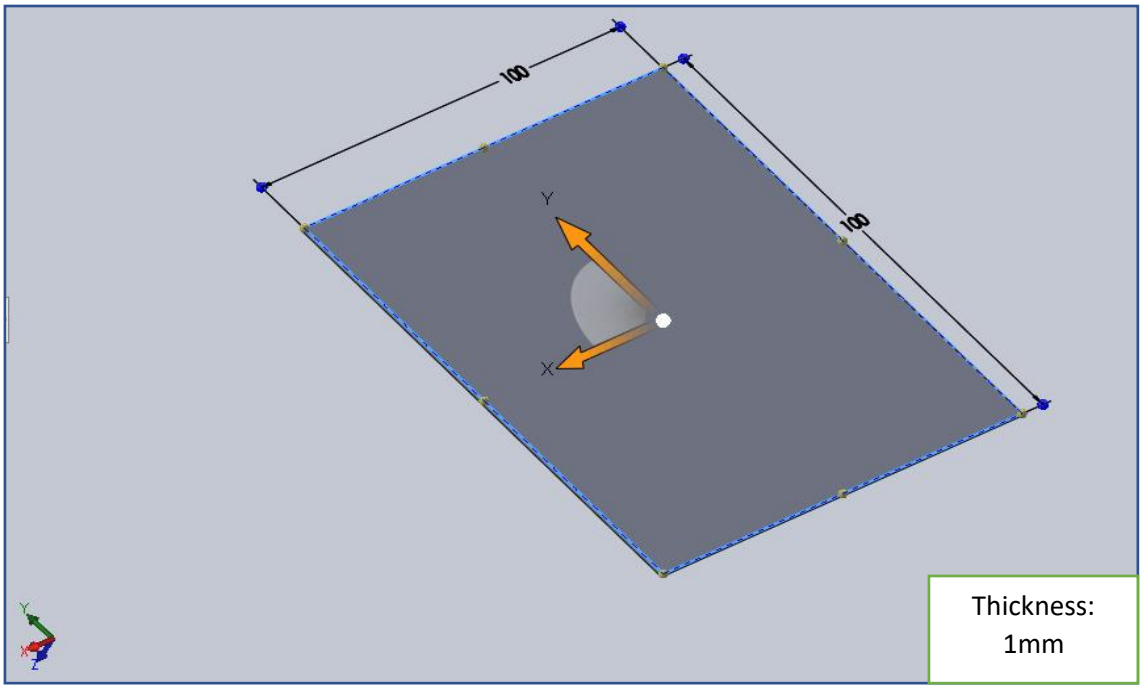


Figure D.3 FTPE board geometry

Details of "Mesh"

Defaults	
Physics Preference	Explicit
Relevance	0
Element Order	Linear
Sizing	
Size Function	Adaptive
Relevance Center	Medium
Element Size	Default
Initial Size Seed	Assembly
Transition	Slow
Span Angle Center	Coarse
Automatic Mesh ...	On
Defeature Size	Default
Minimum Edge L...	1.e-003 m
Quality	
Check Mesh Qua...	Yes, Errors
Target Quality	Default (0.050000)
Smoothing	High
Mesh Metric	None

Figure D.4 Mesh generation

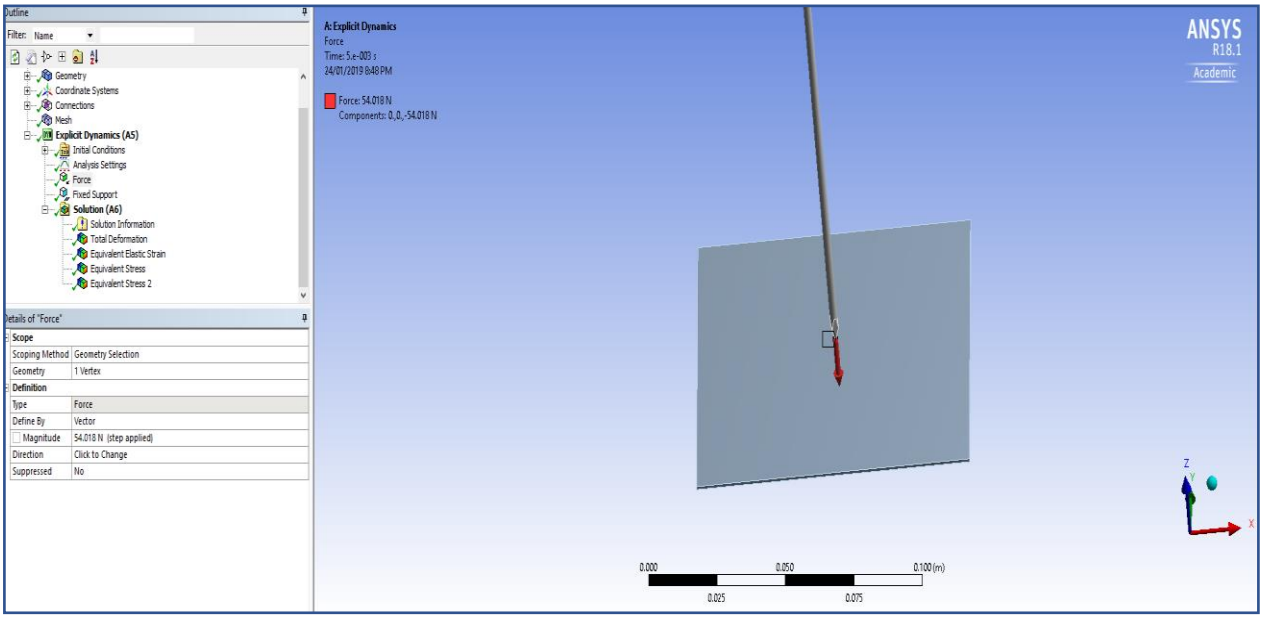


Figure D.5 Apply the load

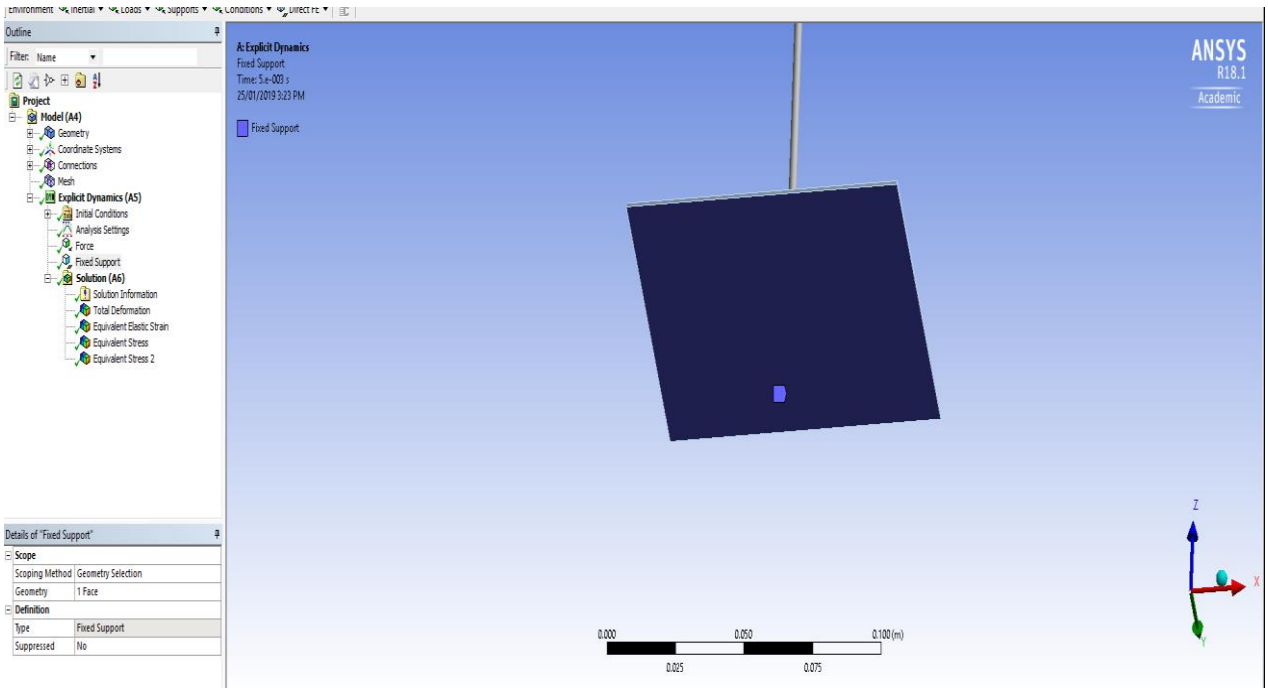


Figure D.6 Apply the constraints

Sensitivity Analysis for the theoretical model relative to mesh size

The mesh size of PTFE board varied from 0.01 to 2 mm, all other parameters were kept consistent. Details are shown in Table D.1. The sensitivity analysis is presented in Figure D.7.

Table D.1 Outcome of varied mesh size

Mesh size (mm)	Stress (10^5 Pa)
0.01	5.6861
0.05	5.6861
0.1	5.6861
0.5	5.6861
1	5.6861
1.5	4.9868
2	4.9868

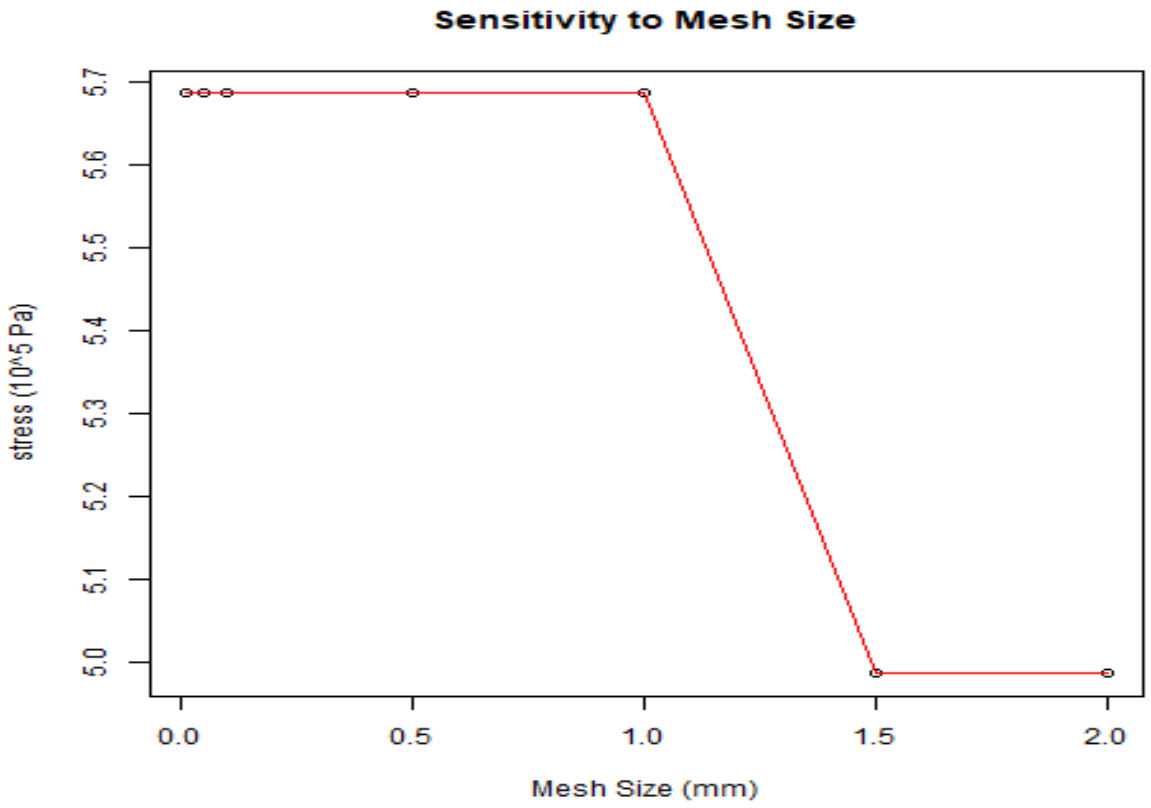


Figure D.7 Sensitivity Analysis for the theoretical model relative to mesh size

APPENDIX E

FINITE ELEMENT MODELING FOR SIMULATION OF RETRACTOR EXPANDING

The stepwise retractor operation simulation procedure in Ansys Workbench is discussed below:

1. Define geometrical object as in Figure E.1 with the parameter given in Figure 5.1 and Figure E.2 within the parameters.
2. Define the type of material as show in Table 5.2.
3. Define the frictional coefficient between two objects as shown in Figure E.3.
4. Add face mesh and sweep mesh method and define the face sizes as shown in Figure E.4 and Figure E.5.
5. Apply load and constraint, the gravity of retractor is applied in Figure E.6 and the force which equals to other 6 pieces is exerted on this piece in Figure E.7, and 5 faces of the intestines are fixed as illustrated in Figure. E.8.
6. Set up the rotational joint and velocity as illustrated in Figure E.9 and Figure E.10 respectively. In later analysis, the velocity would be changed to check the difference of the results.
7. Complete the model.

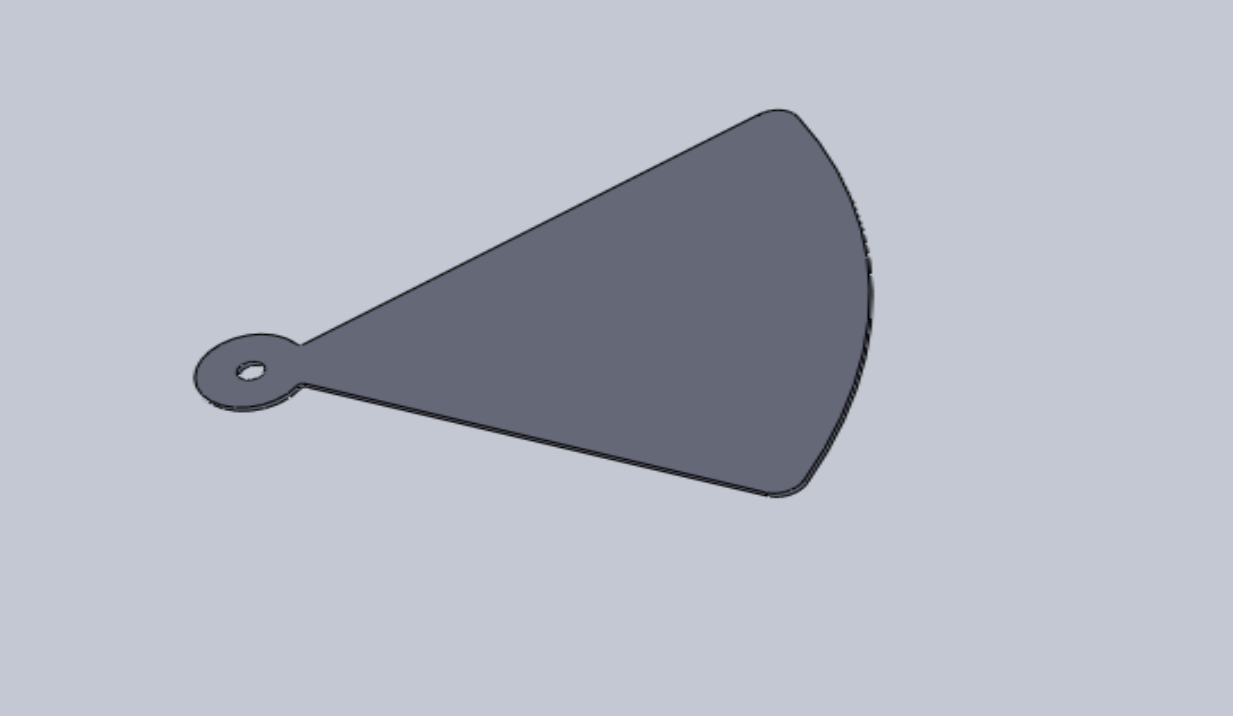


Figure E.1 Retractor geometry

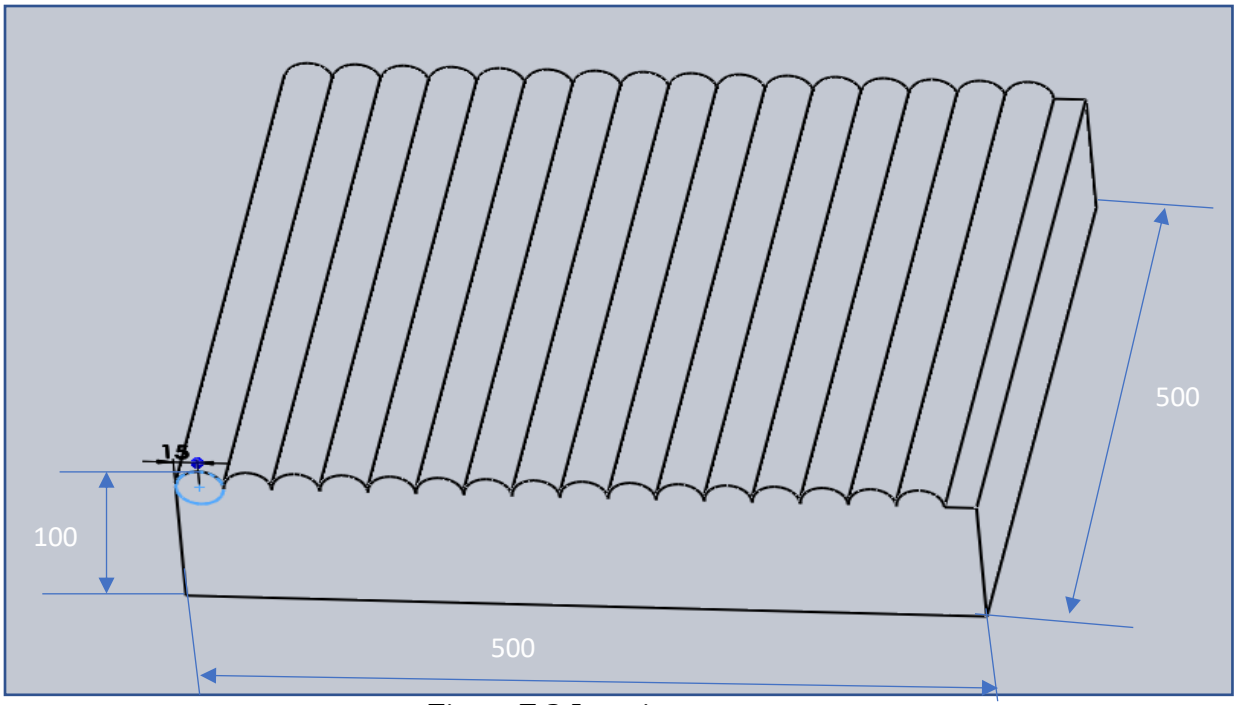


Figure E.2 Intestine geometry

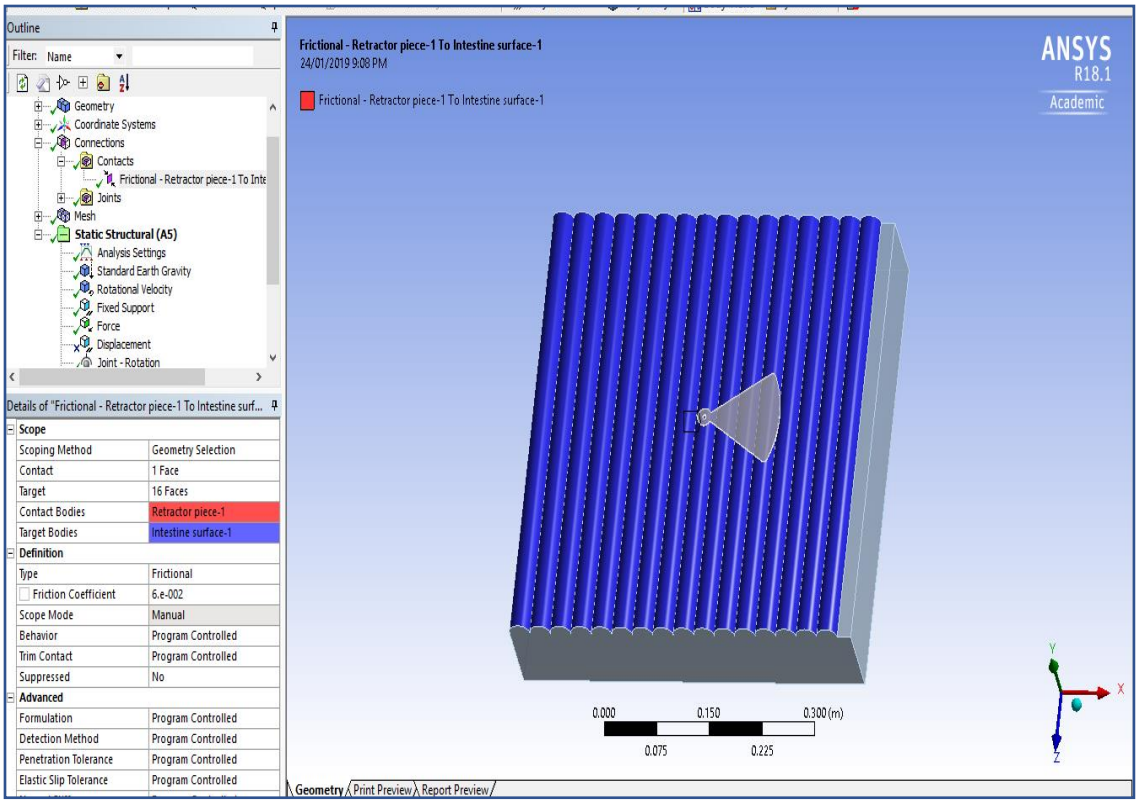


Figure E.3 Frictional coefficient

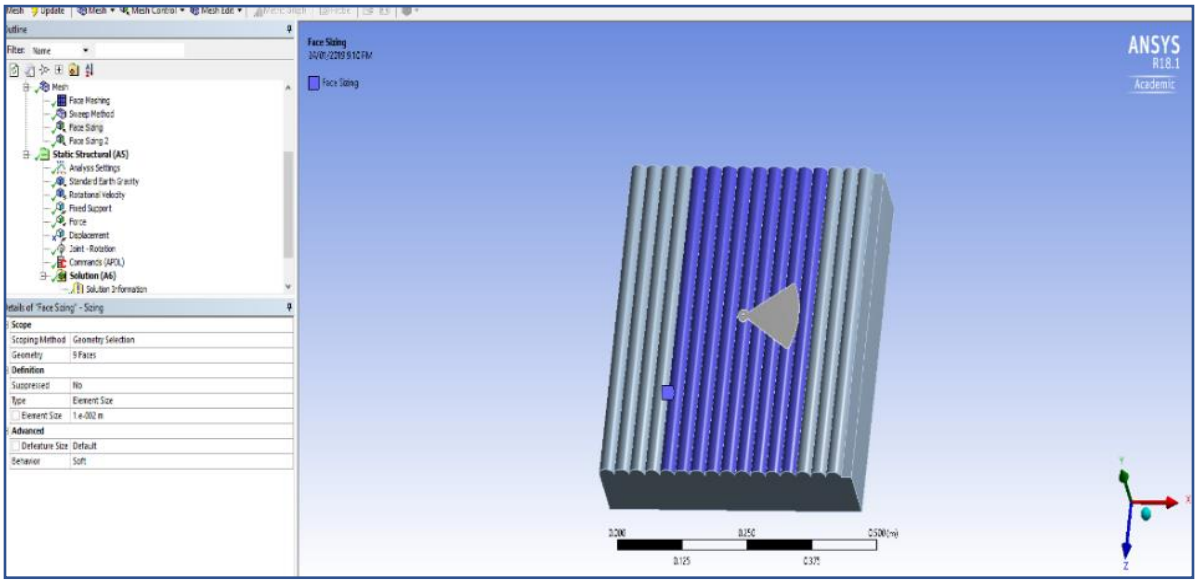


Figure E.4 Face size of intestine

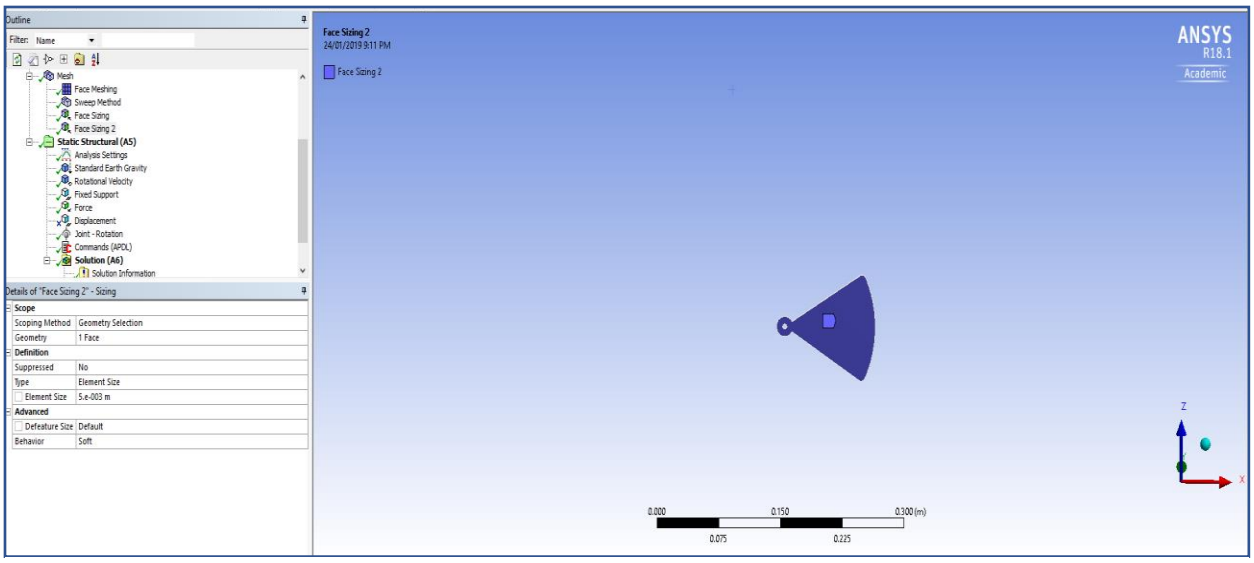


Figure E.5 Face size of retractor

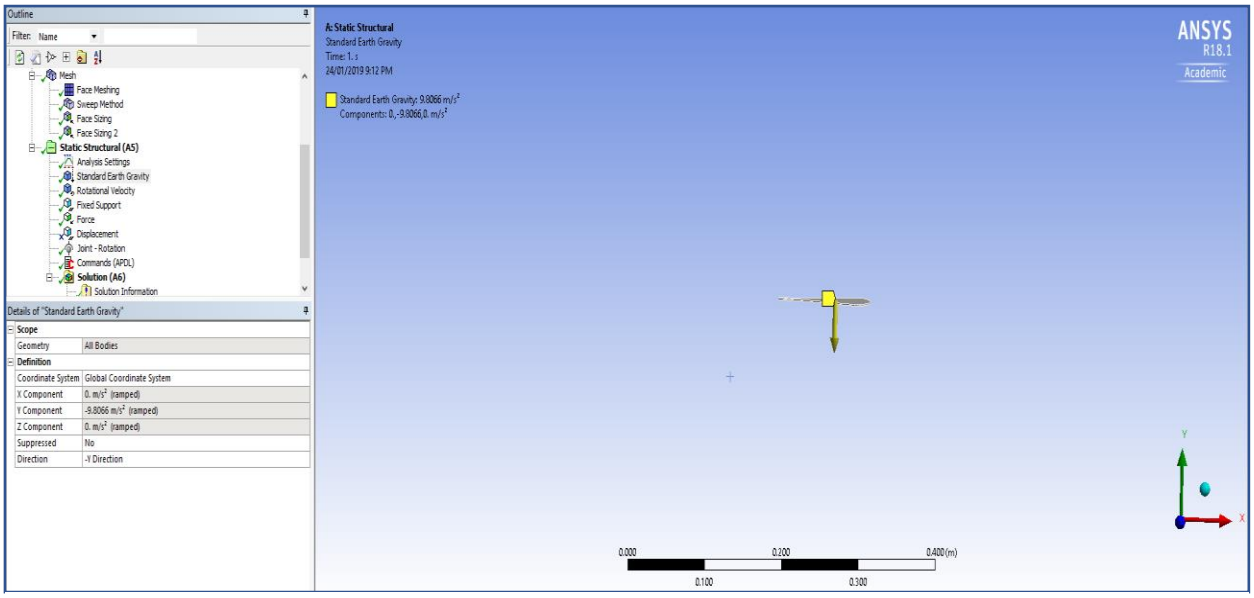


Figure E.6 Gravity load

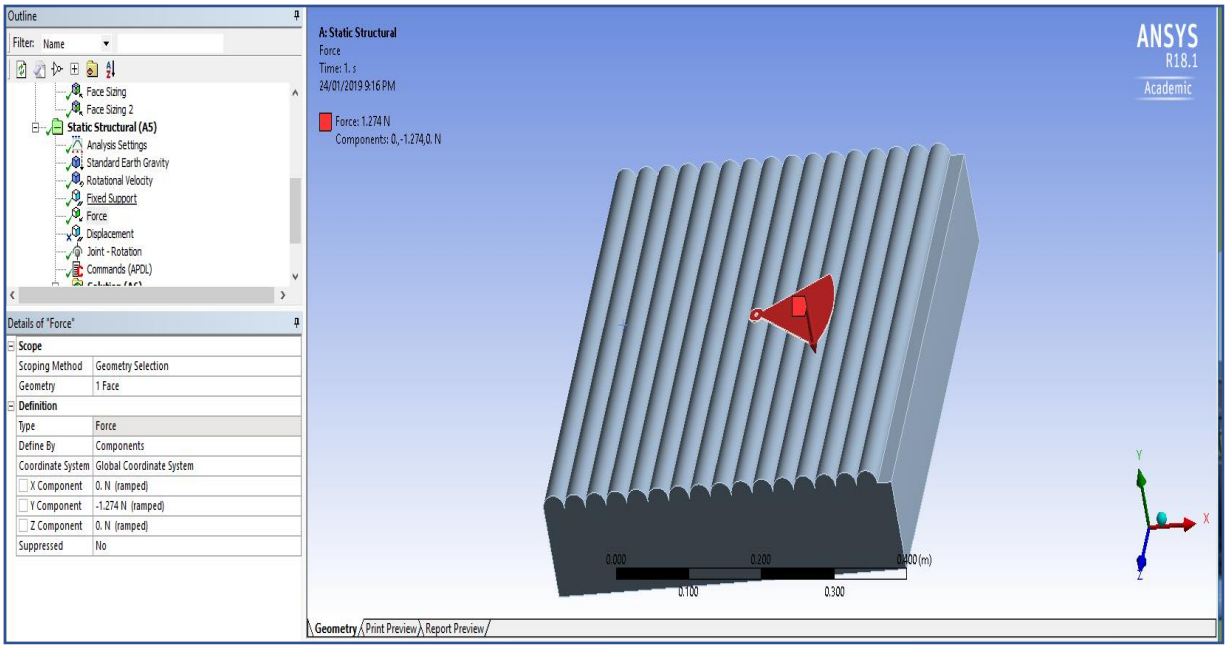


Figure E.7 Gravity equivalent

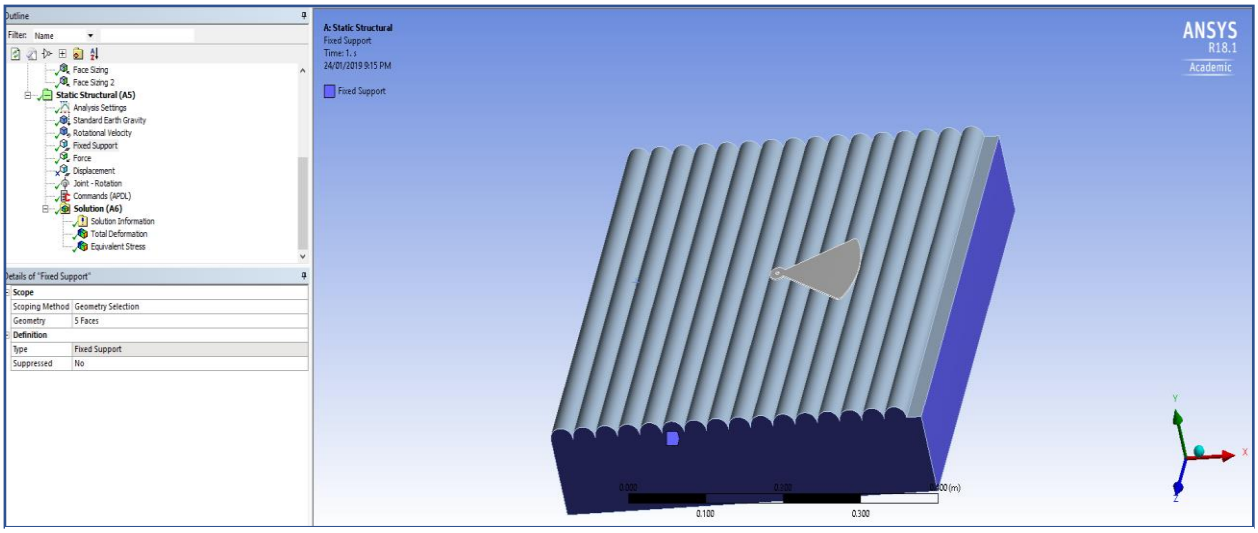


Figure E.8 Fixed support

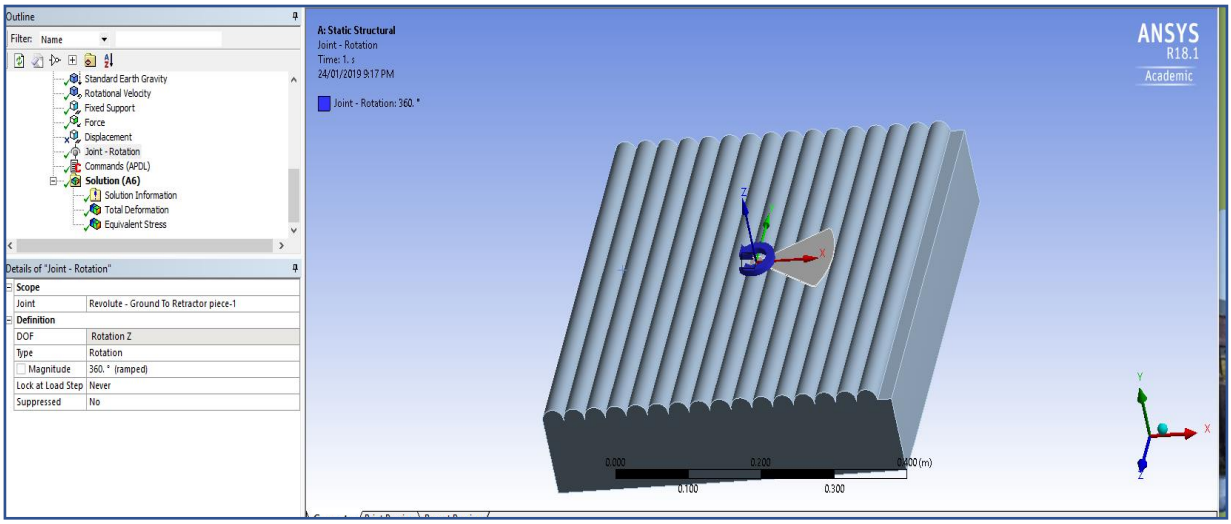


Figure E.9 Set up the rotational joint

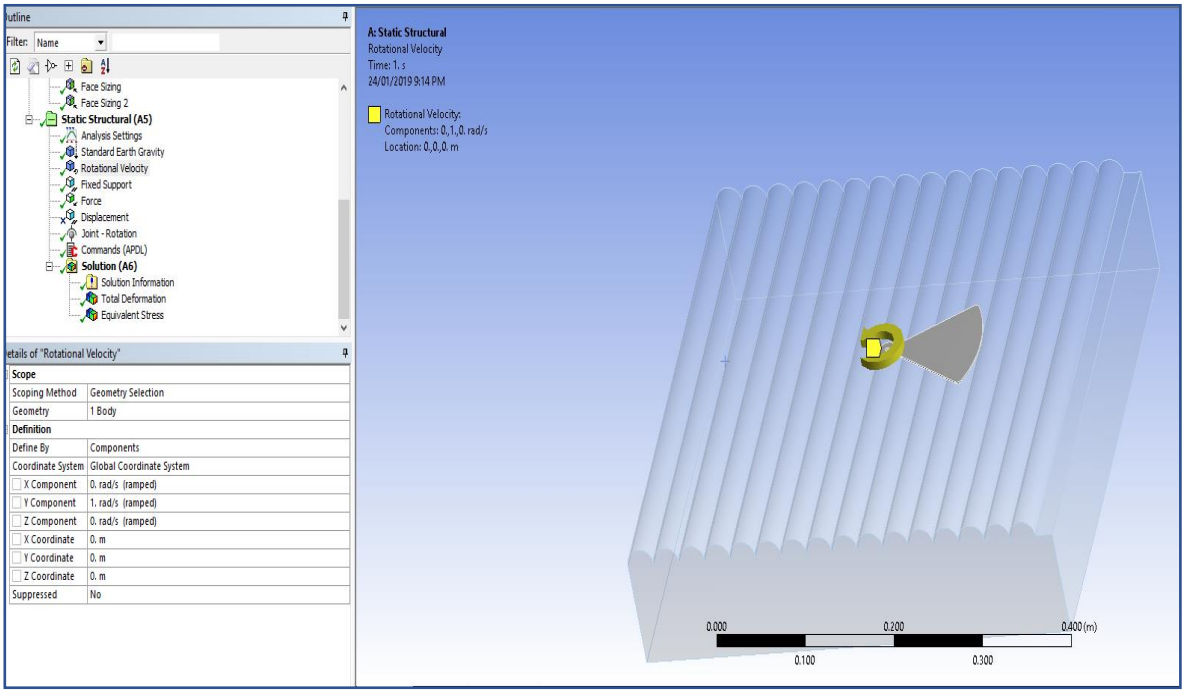


Figure E.10 Set up the rotational velocity

Sensitivity Analysis for the theoretical model relative to mesh size

The mesh size of PTFE board varied from 5 to 30 mm, all other parameters were kept consistent. Details are shown in Table E.1. The sensitivity analysis is presented in Figure E.11.

Table E.1 Outcome of varied mesh size

Mesh size (mm)	Stress (Pa)
5	2136.4
10	1261.2
15	1085.5
20	787.63
25	886
30	934.74

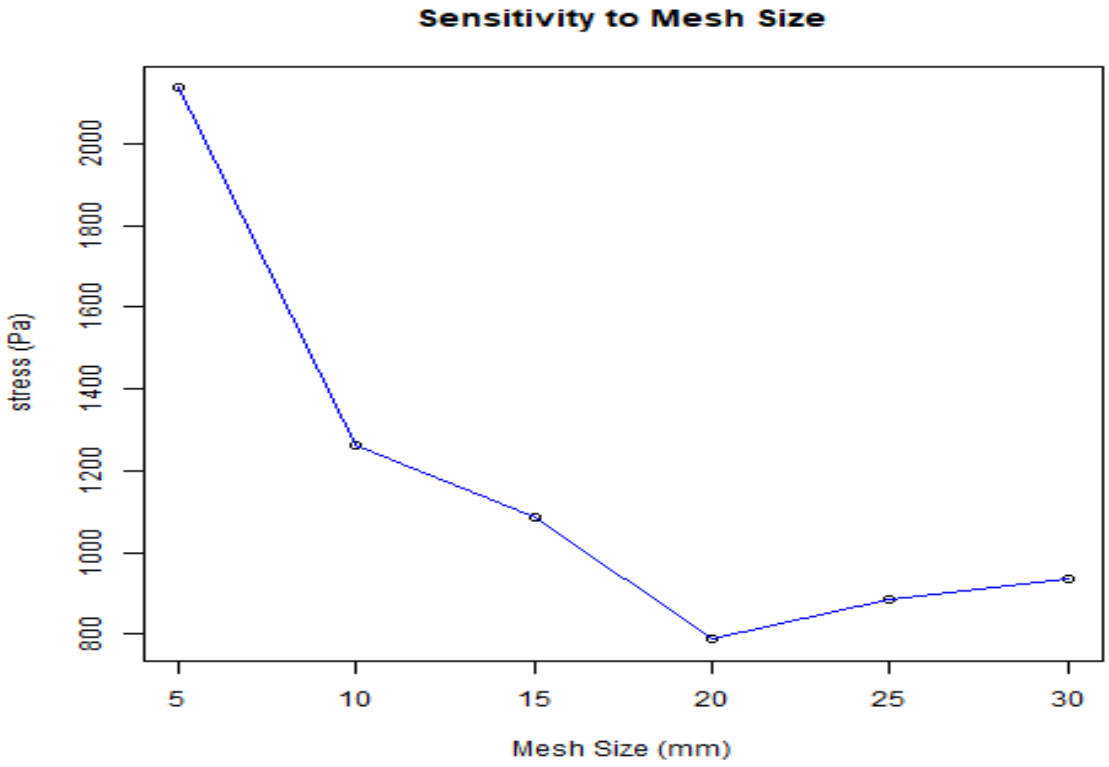


Figure E.11 Sensitivity Analysis for the theoretical model relative to mesh size